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PART II:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

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ANTIBIOTIC, NITROFORAN, AND SULFONAMIDE DRUGS IN ANIMAL FEEDS

Final Regulations

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

[Docket No. 75N-0171]

PART 121—FOOD ADDITIVES

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Antibiotic, Nitrofuran, and Sulfonamide Drugs in the Feed of Animals

The Food and Drug Administration issues a list of manufacturers of medicated premixes and their products in compliance with the provisions of § 558.15 *Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals* (21 CFR 558.15), and deletes from the regulations those manufacturers and products that are subject to, but have not complied with, the requirements for continued marketing set forth in § 558.15. This order shall be effective March 26, 1976.

BACKGROUND

In the FEDERAL REGISTER of February 1, 1972 (37 FR 2444) and April 20, 1973 (38 FR 9811), the Commissioner of Food and Drugs proposed and promulgated, respectively, § 558.15. The Commissioner announced in § 558.15 that he would propose to revoke currently approved subtherapeutic uses in animal feed of antibiotic, nitrofuran, and sulfonamide drugs, whether granted by approval of new animal drug applications (NADA's), master files, and/or antibiotic or food additive regulations, unless data were submitted which resolve conclusively certain issues concerning their safety in man and in animals and their effectiveness. The announced criteria for the resolution of these issues were based on the guidelines included in the report of the FDA Task Force on the Use of Antibiotics in Animal Feeds and developed by the Bureau of Veterinary Medicine. All persons or firms previously marketing drug products identical, related, or similar to those for which approvals were outstanding were required to submit new animal drug applications if marketing was to continue in the interim.

Pursuant to section 512(l) of the Federal Food, Drug, and Cosmetic Act, the Commissioner particularized in § 558.15 criteria that must be met to resolve the issues concerning the safety and effectiveness of these drugs. Section 558.15 (b)(1) required any person interested in developing data which would support retaining approval for subtherapeutic uses of antibiotic, nitrofuran, and sulfonamide drugs to submit to the Commissioner records and reports of completed, ongoing, or planned studies, including protocols, on a prescribed schedule: For the tetracyclines, streptomycin, dihydrostreptomycin, penicillin, and the sulfonamides, by July 19, 1973; for all other antibiotics, by October 17, 1973; and for nitrofuran drugs, by March 4, 1974. Furthermore, § 558.15(c) gave notice that the failure of the sponsor of any drug to comply with any of the provisions included in paragraph (b) of that section or interim results indicating a health hazard would be considered as grounds for proceeding immediately to withdraw approval of the drug for use in animal feeds under section 512(l) of the act (in the case of the failure to submit required records and reports) or section 512(e) of the act (where new information shows that the drug is not shown to be safe).

A notice of proposed rule making was published in the FEDERAL REGISTER of August 6, 1974 (39 FR 28393) to amend § 558.15 by revising paragraph (a) and by adding paragraph (g) (1) and (2). The proposed revision of paragraph (a) was in error. Because the language of the proposal was identical to that already appearing in the CFR, any treatment of the erroneous proposed revision to paragraph (a) has been omitted in this final regulation.

Paragraph (g)(1) was to list the antibacterial drug premixes manufactured by designated sponsors which are eligible for interim marketing based on their compliance with § 558.15(b)(1). Paragraph (g)(2) was to list the drug combinations permitted for inclusion in animal feed, when prepared from the antibacterial premixes listed in paragraph (g)(1), and the sponsors of these drug combinations. In addition, the Commissioner proposed to exempt from the requirements imposed by § 558.15 producers of certain intermediate premixes. The Commissioner concluded (39 FR 28393) that the producers of intermediate premixes need not at this time submit an NADA and the data required under § 558.15 for the interim marketing of any intermediate premix produced solely from a premix that is in compliance with this section, if the intermediate premix contains no drug ingredient whose use in or on animal feed requires an approved NADA pursuant to section 512(m) of the act and/or if the intermediate premix contains a drug for which a specific premix has been approved by regulation in Subpart B of 21 CFR Part 558.

In the same issue of the FEDERAL REGISTER (39 FR 28382), a notice was published proposing to amend 21 CFR Parts 121, 135e (recodified at Part 558 Subpart B), 135g (recodified at Part 556), and 144.26 (recodified at § 510.515) to revoke approvals for those antibacterial drugs intended for use in animal feed which are not in compliance with the requirements of § 558.15. Included in that notice was a proposal to revoke § 558.19 *Combination antibiotic drugs in animal feeds no longer sanctioned*, since the provisions of § 558.19 were otherwise encompassed by the proposed amendments. Certain uses of oxytetracycline and neomycin, alone or in combination with other drugs, which are not the subject of published regulations or for which commitments were not received and for which usages were not listed in the corresponding amendment to § 558.15 were also subject to the proposed revocation.

EFFECT OF THIS ORDER

This order identifies the drug firms and the antibacterial drugs intended for use in animal feeds which they sponsor that are currently in compliance with the provisions of § 558.15 and revokes from the regulations those subtherapeutic uses of antibiotic, sulfonamide, and nitrofuran drugs for which the required commitments, reports, and/or data required by § 558.15 were not filed.

One provision of § 558.15 required all holders of approvals of these new animal drugs and all persons or firms previously marketing identical, related or similar products to file records and reports of completed, ongoing, or planned studies, including protocols, to resolve conclusively the issues concerning their safety to man and animals. Paragraph (g)(1) of § 558.15, as set forth below, is an exclusive list of the antibacterial drug premixes which, because their sponsors have filed commitments to conduct studies that will conclusively resolve the issues concerning the safety of their subtherapeutic usages, are eligible for interim marketing.

Additionally, § 558.15(b)(3) mandated commitments to submit data to demonstrate the effectiveness of these antibacterial drugs for subtherapeutic usage under criteria established by the Bureau of Veterinary Medicine. The Commissioner called for this data to continue the evaluation of the effectiveness of combination animal drug products which was initiated with the promulgation of § 558.19. Changes in the new animal drug review process that began in June 1967 incorporated contemporary scientific criteria to measure the effectiveness of drugs marketed to promote increased rate of weight gain, and/or increased feed efficiency. The effectiveness of most combinations approved since that time has been evaluated using these contemporary scientific criteria. Section 558.15 requires no further determination of effectiveness for combinations determined to be effective under these criteria. The regulation, however, required sponsors of all previously approved subtherapeutic antibacterial combination drugs that had not been evaluated using these criteria to submit a commitment to generate necessary data for these products to be eligible for interim marketing until these data can be reviewed.

Paragraph (g)(2) of § 558.15, as set forth below, lists all drug combinations eligible for interim marketing and the manufacturers who are sponsoring the requisite effectiveness testing. Marketing is permitted only for these combinations and only when they are prepared from the antibacterial premixes listed in paragraph (g)(1). Most of the drugs already approved under these effectiveness criteria have been codified in Subpart B of 21 CFR Part 558; these drugs have been incorporated in paragraph (g)(2) by reference because of the large number of drugs affected and the length of the applicable regulations. The only other drug

combinations that are eligible for interim marketing have either been approved on the basis of the contemporary effectiveness criteria and not been published in Subpart B of 21 CFR Part 558 or have had commitments filed to generate the requisite effectiveness data; all these combinations are listed in paragraph (g) (2).

Commitments to generate data to demonstrate the effectiveness of the individual antibiotics listed in 21 CFR 121.-225 were not required by § 558.15. The National Academy of Sciences—National Research Council, Drug Efficacy Study, concluded, and the Commissioner concurred, that individual antibiotics listed in that section are effective for certain claims regarding increased rate of weight gain (35 FR 11070, 11531, 11646, 11705, 11952, 12490, 13156, and 13401). However, commitments to resolve conclusively the safety issues posed by these drugs were required. These antibiotics are safe and effective for use under contemporary standards, and commitments to conduct studies that will conclusively resolve the issues concerning their safety raised by § 558.15 have been filed. Therefore, these antibacterial drugs are eligible for interim marketing, and they have been listed in paragraph (g) (2) together with their sponsors.

The Commissioner is also amending 21 CFR 510.515 (formerly 21 CFR 144.26). This regulation lists those antibiotics intended for use alone or in combination with other drugs in animal feeds that are exempt from the certification requirements of section 512(n) of the act, and the Commissioner has revised this regulation to revoke any prior exemption from certification for which the commitments required by § 558.15 were not submitted.

Comments on the proposal were received from 15 firms engaged in the manufacture of drugs used in the production of medicated feeds. Comments were also received from an association of animal drug manufacturers and an association of animal feed manufacturers on behalf of their respective members. Several comments raised questions respecting the procedures being followed to revoke the unsponsored uses of these drugs; however, most of the comments from the drug and feed manufacturers were concerned with the proposed deletion from the regulations of specific antibiotic combination drugs.

The principal comments received and the Commissioner's conclusions regarding them are as follows:

1. A trade association requested that due consideration be given to comments of its member firms and requested that the August 6, 1974 announcement and the September 27, 1974 correction be republished as a single proposal if they contain a substantial number of errors.

The Commissioner concludes that this order need not be republished as a proposal. Each comment has been carefully evaluated to determine which drugs, if any, were incorrectly proposed for revocation from the regulations and which drugs and drug sponsors, if any, were improperly omitted from the appropriate lists in paragraph (g) (1) and (2) of § 558.15. In addition, all comments submitted pursuant to requirements imposed by § 558.15 have been reviewed to assure the accuracy of the regulations as set forth below. Provisions of the regulations that were erroneously deleted or omitted in the proposals have been restored.

2. Several comments stated that the regulations, as proposed, would prohibit the marketing of products which are covered by approved NADA's or which are "deemed approved" by the transitional provisions of the Animal Drug Amendments of 1968. The comments stated that approval of these drug products may not be withdrawn through publication of a proposed rule, but must be withdrawn in accordance with provisions of section 512(e) of the act including, as provided therein, giving notice of opportunity for hearing for the specific NADA's involved.

The Commissioner concludes that the procedure used to withdraw approval of these NADA's satisfies the requirements of the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act. As proposed in the FEDERAL REGISTER of February 1, 1972 (37 FR 2444) and promulgated in the FEDERAL REGISTER of April 20, 1973 (38 FR 9811), § 558.15(c) states that the failure of any sponsor of an NADA for the use at subtherapeutic levels of any antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals to comply with the requirements of the regulation will be considered grounds for immediately proceeding to withdraw approval of the NADA for failure to comply with section 512(1) of the act. Section 512(e)(2) of the act permits the Secretary, after due notice and opportunity for hearing to withdraw approval of the NADA for failure to comply with section 512(1) of the act. Thus compliance with § 558.15 is properly required as a condition for continued approval of an NADA.

The proposed deletion of regulations published in the FEDERAL REGISTER of August 6, 1974 (39 FR 28382) constituted specific public notice of the Commissioner's determination that the drugs listed therein (as subsequently amended) were not in compliance with § 558.15(b) and that such drugs were therefore subject to withdrawal of approval pursuant to § 558.15(c). Similarly, the companion notice of proposed rule making also published on August 6, 1974 (39 FR 28393) afforded public notice to all sponsors of those drugs for which commitments to conduct the required safety and/or effectiveness studies had been filed pursuant to § 558.15 that they were in compliance with the regulation.

This procedure of providing notice by FEDERAL REGISTER publication was used because many of the drugs involved were originally marketed pursuant to antibiotic and food additive regulations, and the agency had previously exempted these drugs from the antibiotic batch certification requirements and Form FD–1800 requirements. The Commissioner was therefore not able to identify all persons who had legally been marketing these drugs. The August 6, 1974 notice of proposed rule making, in combination with the proposed deletion of the regulations, afforded adequate notice to sponsors of antibacterial drugs not listed in paragraph (g) (1) and (2) of § 558.15 that they had failed to comply with § 558.15(b), and that such drugs were therefore subject to withdrawal of approval in accordance with § 558.15(c). Having failed to file responses demonstrating that their products are in compliance with the requirements of § 558.15 or that the regulation is, or should be, inapplicable, sponsors of drugs for which approvals are hereby withdrawn have not shown the necessity for a hearing at which the only issue could be whether those requirements have been met.

The Supreme Court has recognized that class regulation through rule making is legally permissible and, indeed, often preferable to case-by-case adjudication. See, e.g., *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620–622 (1973); *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973); *Federal Power Commission* v. *Texaco*, 377 U.S. 33, 39–41 (1964); *United States* v. *Storer Broadcasting Co.*, 351 U.S. 192, 202–205 (1956). In this instance, the Commissioner has particularized the statutory standards for continued approval of NADA's by promulgating § 558.15. No hearing need be afforded an applicant whose submissions, after proper notice, on their face fail to meet the requirements for NADA approval or to provide reasons why approval of its NADA should not be withdrawn.

The Commissioner concludes that all interested persons have been afforded ample opportunity to participate in the development of the requirements contained in § 558.15 and to comply with those requirements or offer reasonable explanation for failure to comply. Accordingly, all applicable legal standards have been met and approval of the NADA's involved may properly be withdrawn by regulation.

3. One comment suggested that each distributor for whom a distributor's supplemental NADA has been filed by the holder of the approval should be listed as a sponsor of the drug in paragraph (g) (1) or (2) if the holder of the approval is in compliance with the requirements of § 558.15. This comment contended that the failure to list every approved distributor would cause confusion and would place distributors at a competitive disadvantage because products that do not carry the name of a listed sponsor will inevitably suffer in the marketplace.

The Commissioner does not agree with this suggestion. Section 512(l) of the act provides for the publication in the FEDERAL REGISTER of the name and address of the applicant (i.e., the sponsor) of an approved NADA. A distributor (unless he is also the sponsor of the NADA) is not an "applicant" within the meaning of section 512(l) but simply a person who distributes under his own label a product manufactured and labeled for him by one who is an applicant. Thus, there is no legal requirement that the

names of distributors be published and it has never been Agency practice to do so. Listing distributors would impose an unwarranted burden on the Agency because of the large number of distributors and their propensity to change suppliers. Moreover, where a distributor wishes to do so, there is no bar to his listing on a drug label the names of both the manufacturer and the distributor of the product provided it is done in such a manner as to reveal clearly the connection (i.e., as manufacturer or distributor) each person or firm has with the product. Therefore, the Commissioner concludes that distributors should not be listed in § 558.15.

4. Four comments opposed deletion from the regulations of a limited number of drug products containing antibacterials in therapeutic concentrations which do not have a 14-day limit on their use. The comments stated that § 558.15 implements the recommendations of the FDA Task Force on the Use of Antibiotics in Animal Feeds, which directed its attention to the continuous use of subtherapeutic levels of antibacterial drugs in animal feeds, and the marketers were not given proper notice to comply with the requirements established by that regulation.

The Commissioner advises that the Task Force was concerned with the health hazard associated with the subtherapeutic use of antibacterial drugs in animal feeds. After the promulgation of § 558.15, a determination was made that the use of any antibacterial drug continuously in feed for longer than 14 days should be considered a subtherapeutic usage, and the Commissioner concluded that sponsors of antibacterials intended for such use must meet the requirements established in the regulation regardless of the concentration of the antibacterial agents in the drug products. This policy was made known to a number of drug sponsors as questions arose on individual products, but the requirement was not included in either the proposed or final regulation. The Commissioner concludes that sponsors of antibacterial drug products intended for use in animal feeds for treatment of disease for more than 14 days were not provided adequate notice that the requirements established by § 558.15 were applicable to them. Therefore, the proposed deletion of these antibacterial products from the regulations is vacated.

This decision does not undermine the impact of the regulation. The use of antibacterial drugs in animal feeds ordinarily is not the preferred route of administration when treating an animal disease. Animals manifesting clinical symptoms of disease in most cases consume abnormally small amounts of feed. Therefore, the successful treatment of the disease is often hindered by difficulty in maintaining adequate drug exposure. This fact, together with the cost involved in feeding therapeutic levels of antibacterial drugs for greater than 14 days, leads the Commissioner to conclude that use of these drug products at therapeutic levels in feeds constitutes a very small segment of the antibacterial drug market.

Finalization of the actions concerning the feed-use products evaluated by the National Academy of Sciences—National Research Council, Drug Efficacy Study, will deal with each of these products. Where appropriate, claims for treatment of disease will be limited to prescribed durations. Furthermore, should the studies of the subtherapeutic uses of these antibacterial agents being conducted pursuant to § 558.15 generate new evidence that undermines his previous conclusions as to the safety of these antibacterials, the Commissioner will propose to withdraw their marketing approvals.

5. Questions have arisen concerning the marketing status of products that combine diethylstilbestrol (DES) with a subtherapeutic antibacterial. Section 558.15 requires all persons marketing subtherapeutic antibacterials for approved uses to file commitments to conduct studies that will conclusively resolve the issues of the safety of the use of the antibacterial ingredients and the effectiveness of the combination products on the basis of contemporary scientific testing criteria. However, because the Food and Drug Administration took regulatory action against DES before § 558.15 was promulgated, the impact of this regulation on the DES-antibacterial combinations has never been clearly enunciated.

Between the notice of proposed rule making to require safety and effectiveness data for subtherapeutic uses of antibiotics on February 1, 1972 (37 FR 2444), and the publication of the final order on April 20, 1973 (38 FR 9811), the Food and Drug Administration withdrew approval of all NADA's for DES liquid and drug premixes. Presumably because all approvals were withdrawn, no drug sponsors filed commitments to conduct the required studies for the DES-antibacterial drugs for subtherapeutic use. On January 24, 1974, the United States Court of Appeals for the District of Columbia Circuit held that the Agency's notice to holders of DES NADA's was inadequate as a basis for withdrawing their approval without a hearing, and reinstated both the approval of the NADA's and the accompanying regulations. *Hess & Clark, Division of Rhodia, Inc.* v. *Food and Drug Administration*, 495 F. 2d 975 (D.C. Cir. 1974). Formal confirmation of reinstatement of the regulations was published in the FEDERAL REGISTER of February 27, 1975 (40 FR 8329).

In the FEDERAL REGISTER of August 6, 1974 (39 FR 28382 and 28393) and September 27, 1974 (39 FR 34682), the Commissioner issued a proposal to list all drugs and sponsors which were in compliance with § 558.15 and to revoke approval of all drugs not in compliance. No holders of approvals for DES combinations have ever filed either commitments to conduct the required studies, or comments objecting to omission of these combinations from the proposed list of sponsored combinations eligible for marketing and from Part 121 (21 CFR Part 121).

Although the Food and Drug Administration might therefore be legally justified in taking immediate action against these combination products, the Commissioner acknowledges that the Agency's February 1975 reinstatement of the DES regulations pursuant to the Court of Appeals' order may have misled the sponsors as to the status of these products. The Commissioner has reviewed the situation concerning these products and concludes that immediate final action against them is inappropriate at this time. At the same time, they remain subject to the requirements of § 558.15 of the regulations and section 512(1) of the act. The Commissioner has therefore determined that § 558.15 should be modified to clarify the status of DES-antibiotic combination products as follows:

In accordance with § 558.15, all marketed DES-subtherapeutic antibacterial combinations must contain antibacterials for which commitments to conduct the necessary safety studies have been filed and which are listed in paragraph (g)(1) of that section. Moreover, after reviewing the information available about the DES-subtherapeutic antibacterial combinations, the Commissioner has determined that no approvals for these combinations are supported by efficacy data that meet contemporary scientific criteria. For this reason, all sponsors of previously approved DES-subtherapeutic antibacterial combinations must file commitments to conduct studies satisfying these criteria to demonstrate the effectiveness of their products. Such commitments must be filed by March 26, 1976, which is more than 1 year after formal reinstatement of the DES regulations, the latest date on which makers of the DES combinations could plausibly believe that § 558.15 was inapplicable to their products. Any conscientious sponsor, therefore, will have sufficient opportunity to comply with the regulation. Because the sponsors should have filed commitments and begun studies immediately after the January 24, 1974 decision of the Court of Appeals in *Hess & Clark, supra*, and because the necessary affectiveness studies require less time than the safety studies, data satisfying contemporary efficacy criteria must be submitted by March 26, 1977. All other provisions of § 558.15 are also applicable to these drugs. Only persons holding approvals for these combinations may market them in the interim; study progress reports must be filed every January 1 and July 1 until completion; and all provisions of § 558.15(c) concerning failure to submit required records and reports apply. Additionally, the extraordinary fact situation concerning the drugs requires further assurance of immediate compliance with the regulation as instituted. Therefore, the first progress reports demonstrating initiation of the studies must be filed by April 26, 1976.

DES subtherapeutic-antibacterial comcombinations fell within the scope of the Agency's original notice of proposed

rule making on this matter, and sponsors of such products have had ample opportunity to demonstrate that § 558.15 was inapplicable or should be waived. No comments were filed, and these combinations may be regulated by § 558.15 as promulgated. Manufacturers of the combinations containing DES have already enjoyed an economic advantage over similarly situated sponsors of other antibacterial combinations. The Commissioner therefore concludes that the requirements herein set forth may be promulgated as a final order.

In the FEDERAL REGISTER of January 12, 1976 (41 FR 1804), the Food and Drug Administration issued a Notice of Opportunity for Hearing proposing to withdraw approval of all outstanding NADA's for the use of DES in animals used for human food, on the grounds that residues in animal tissue produced by the use of such products have not been shown to be safe and that the Delaney anticancer clause is applicable because no adequate methods exist that are capable of detecting and measuring residues of DES at levels above any that have been shown to be safe. The notice afforded holders of NADA's for DES an opportunity to request a hearing on the proposed withdrawal of approval and to demonstrate that disputed issues of material fact exist that require a hearing. Any hearing held in response to proper requests that are received is likely to occur during the first 6 months of 1976. To avoid any future misunderstanding, the Commissioner announces that, should a final Agency decision withdrawing approval of DES for use in animals used for human food be issued before the dates specified for final submission of data supporting the safety and efficacy of DES-antibacterial combination products, this order will not authorize the continued marketing of these combination products pending the completion and submission of the required studies.

6. Questions have arisen about the impact on § 558.15 of *Hoffmann-LaRoche* v. *Weinberger*, Civil Action No. 75-0272 (D.D.C., filed July 27, 1975).

Section 558.15 serves three functions: Principally, it requires submission of data to resolve the safety and effectiveness questions pertaining to the use of subtherapeutic antibacterial drug combinations. Secondly, it provides the Agency with documentation of the marketing of subtherapeutic antibacterial combinations transitionally approved by section 108 of the Animal Drug Amendments and requires these files to be supplemented with contemporary scientific data. Finally, it establishes the conditions under which products containing subtherapeutic levels of antibacterial drugs for use in animal feed may continue to be marketed. These requirements permit FDA more efficiently to regulate the marketing and use of these drugs.

The decision in *Hoffmann-LaRoche* clarifies the scope of § 558.15. The Commissioner has thoroughly reviewed the files on all drugs and sponsors for which the commitments were received to conduct the studies required by this regulation, and the only drugs and sponsors which the Commissioner has determined to be approved for use by NADA, NDA, master file, antibiotic regulation or food additive regulation have been listed. NADA's for drugs subject to the regulation that were filed by persons or firms that did not have, and in some instances may not have been required to have, an approval for marketing are being processed as part of the review required by § 558.15.

7. Whitmoyer Laboratories, Inc., questioned the proposed deletion of the carbarsone-bacitracin methylene disalicylate drug combination (item c) from § 121.310(b) and the failure to list the combination in § 558.15(g)(1) because Whitmoyer holds an approved NADA for the carbarsone combination for use in turkey feed.

The Commissioner concludes that safety studies are being conducted pursuant to § 558.15 by the sponsors of bacitracin methylene disalicylate, and Whitmoyer Laboratories, NADA for the carbarsone-bacitracin methylene disalicylate combination was approved under contemporary efficacy criteria. Therefore, the Commissioner is vacating the proposed revocation of this drug combination from the regulations.

Addition of the drug combination to paragraph (g)(1), however, would be incorrect. Paragraph (g)(1) lists only the manufacturers sponsoring studies to demonstrate the safety of specific antibacterial premixes, and the drug combination is not a premix. Paragraph (g)(2), on the other hand, lists the drug combinations permitted for inclusion in animal feed when prepared from a premix in paragraph (g)(1) and the sponsors of these drug combinations. The NADA for Whitmoyer's combination product was approved under contemporary efficacy criteria, and the required safety studies are being conducted by the sponsor of the antibacterial premix. Because the drug combination meets the criteria established for interim marketing, the Commissioner has added Whitmoyer Laboratories, Inc., and this drug combination to paragraph (g)(2).

8. Norwich Pharmacal Company commented that indications for the use of nihydrazone in § 121.237(d), item 1, should not include claims for the coccidial species *E. maxima* or *E. brunetti*, or the claim for histomoniasis (black head).

As required by § 558.15, commitments have been filed to conduct studies to generate data to support the effectiveness of the nihydrazone drug combinations for the subtherapeutic indications of use set forth in § 121.237. The Commissioner, however, has not conducted a reevaluation of the data available to support the effectiveness claims of nihydrazone as a single ingredient for other indications of use. Nihydrazone, as a single ingredient, was approved for use, among other things, against histomoniasis (black head) and coccidiosis caused by *E. maxima* and *E. brunetti*. The Commissioner concludes that this order is not appropriate for the revision of the approved uses for single ingredient new animal drugs that do not involve subtherapeutic claims. Such a revision would involve drugs whose sponsors were not given appropriate notice to substantiate these claims of effectiveness. Revisions of this nature are more appropriately handled in a separate specific notice giving all holders of approvals for this drug an opportunity to support these indications of use with a well-organized and full-factual analysis of the data to support its effectiveness. This action can be more efficiently handled when all safety and effectiveness data generated pursuant to § 558.15 have been submitted and reviewed. At that time the Commissioner will determine whether the withdrawal of approval of any or all NADA's for nihydrazone drugs is appropriate. Therefore, the Commissioner disagrees with the contention that the indications for use of nihydrazone against coccidiosis caused by *E. maxima* and *E. brunetti* or histomoniasis (black head) should be deleted from the regulations in this order.

9. The notices of August 6, 1974 proposed the deletion from § 558.105(f)(1) of buquinolate 75 grams per ton in finished feed for chickens in combination with: (iv) penicillin, 2.4 to 50 grams per ton; (v) bacitracin, 4 to 50 grams per ton; (vi penicillin plus bacitracin, 3.6 to 50 grams per ton (not less than 0.6 gram of penicillin nor less than 3 grams of bacitracin); and (vii) chlortetracycline, 200 grams (§ 558.105(f)(1) (iv) through (vii) was formerly § 135e.35(f), item 5. a through d). Norwich Pharmacal commented that the efficacy requirements for these drug combinations had been satisfied under contemporary efficacy criteria and that safety studies are being conducted pursuant to § 558.15 for penicillin alone, bacitracin alone, and chlortetracycline alone. On this basis Norwich requested that these drug combinations not be revoked from the regulations.

The Commissioner concludes that these drug combinations have been approved under contemporary efficacy criteria and that the required studies are being conducted to demonstrate the safety of penicillin, bacitracin, and chlortetracyline. Therefore, the Commissioner is vacating the proposed revocation of § 558.105(f)(1) (iv), (v), and (vii).

Because of the difficulty and complexity of research required by § 558.15 in the safety area, the Commissioner further concludes that, at the present time, the safety issues concerning bacterial drug resistance and resistance transfer caused by subtherapeutic antibacterial drug combinations should be first evaluated on the basis of studies that assess the safety of the antibacterials individually. The questions raised by § 558.15 are scientifically complex, and in many instances no model systems for testing are available. Research on a single antibacterial drug minimizes the variables in the studies, prevents masking of untoward effects, and produces more definitive data on the influence of the drug

on animal bacteria. Furthermore, the data may conclusively resolve the theoretical questions raised.

For these reasons the Commissioner concludes that these studies to demonstrate the safety of penicillin alone and bacitracin alone are sufficient to permit the interim marketing of penicillin-bacitracin drug combinations, and the Commissioner is vacating the proposed revocation of § 558.105(f)(1)(vi).

10. Merck & Company questioned the absence from § 558.15 of a provision for a combination drug product containing procaine penicillin-streptomycin administered in drinking water.

The Commissioner advises that the deliberations and conclusions of the FDA Task Force on the Use of Antibiotics in Animal Feeds were directed at the use of antibacterial agents administered to animals in feeds. For this reason, the Commissioner has not included in § 558.15 drugs administered in other dosage forms, such as those administered in drinking water. The safety and effectiveness of drugs administered in these dosage forms are being independently considered.

11. Merck & Company also objected to the failure to list in § 558.15(g) (1) and (2) certain antibacterial premixes and drug combinations for which the firm is sponsoring safety or effectiveness studies, and the concurrent proposed revocation of the corresponding regulations for the drug combinations.

The Commissioner agrees that Merck is sponsoring studies to demonstrate the safety of a penicillin-streptomycin premix. Therefore, Merck and this premix have been added to § 558.15(g)(1) with the indications for use set forth in §§ 121.225 and 121.256 (21 CFR 121.225 and 121.256). Because Merck is conducting studies to resolve the safety issues concerning this penicillin-streptomycin premix for these indications of use, the drug combinations made from this premix for which Merck is also conducting appropriate effectiveness studies may be validly marketed. These drug combinations and their sponsor, Merck, have been added to § 558.15(g)(2), and the proposed revocation of these drug combinations from § 121.256 is vacated.

Merck is also sponsoring effectiveness studies for the following drug combinations which contain erythromycin 4.6 to 18.5 grams per ton and are listed in § 121.210(c) (21 CFR 121.210(c)), table 1, items 2.1, 2.2, 2.3, and 2.4: amprolium 113.5 to 227 grams per ton, amprolium 113.5 to 227 grams per ton plus ethopabate 3.6 grams per ton, amprolium 113.5 to 227 grams per ton plus arsanilic acid 90 grams per ton, and amprolium 113.5 to 227 grams per ton plus ethopabate 3.6 grams per ton plus arsanilic acid 90 grams per ton. Since Abbott Laboratories, Inc. is sponsoring studies to resolve the safety issues concerning the erythromycin premix, these drug combinations may be marketed during the interim period. Therefore, the Commissioner has restored these amprolium combinations to § 558.15(g)(2) with Merck as their sponsor, and the proposed revocation of these regulations is vacated.

12. Commercial Solvents Corporation commented that it is conducting studies pursuant to § 558.15 to resolve conclusively the safety issues concerning zinc bacitracin. In addition, the company filed commitments to conduct studies to demonstrate the effectiveness of the following drug combinations:

a. Zinc bacitracin, amprolium, and ethopabate;

b. Zinc bacitracin, amprolium, ethopabate, and 3-nitro-4-hydroxyphenylarsonic acid;

c. Zinc bacitracin and arsanilic acid; and

d. Zinc bacitracin, zoalene, and 3-nitro-4-hydroxyphenylarsonic acid.

The firm objected to the omission of these drug combinations from § 558.15(g)(2) and the proposed deletion of these drug combinations from Part 121 (21 CFR Part 121).

The Commissioner concludes that Commercial Solvents Corporation has filed commitments to resolve the safety of zinc bacitracin and to demonstrate the effectiveness of the drug combinations in question. Therefore, these drug combinations are eligible for marketing. The Commissioner has listed these drug combinations in § 558.15(g)(2) and is vacating the proposed deletion of these drug combinations from Part 121.

13. Elanco Products Company objected to the proposed deletion of various drug combinations containing hygromycin B for subtherapeutic usage from §§ 121.210 and 121.213 on the grounds that Elanco is sponsoring studies to resolve conclusively the safety of this drug.

Hygromycin B premix and drug combinations containing this drug are within the purview of § 558.15. The Commissioner concludes that the hygromycin B drug combinations proposed for deletion from the regulations are not supported by evidence of effectiveness meeting contemporary scientific criteria, and neither Elanco nor any other drug sponsor has submitted commitments to conduct studies to generate data to demonstrate the effectiveness of the hygromycin B drug combinations, which is also required by § 558.15. Therefore, the Commissioner further concludes that these drug combinations are properly deleted from the regulations.

14. Salsbury Laboratories objected to the proposed revocation of § 121.263, 3-5 dinitrobenzamide; § 121.264, sulfanitran; and § 558.35(g) (5) through (7) (formerly § 135e.31(g), table item 2a.2, b.2, and c.2), aklomide, because these drugs do not exhibit antibacterial activity under any currently approved uses when used as single ingredients and thus are not subject to § 558.15.

The Commissioner concludes that the requirements established by § 558.15 are inapplicable to these drugs when they are used as single ingredients because they are not antibacterials. Nevertheless, the requirements are applicable when these drugs are combined with antibacterials. To market any such combination, a drug sponsor must have filed a commitment to conduct studies to resolve conclusively the issues concerning the safety of the antibacterial component. In addition, adequate effectiveness data meeting contemporary scientific criteria must be included in an approved NADA for the drug or the sponsor must have filed a commitment to conduct studies to generate such data.

The Commissioner has determined that § 121.263 lists no 3,5-dinitrobenzamide-antibacterial combination drugs and, thus, is vacating the proposed revocation of that section.

Sulfanitran-antibacterial combinations were listed in § 121.264(e), and aklomide - antibacterial combinations were listed in § 558.35 (formerly § 135e.31). None of these antibacterial drug combinations has been evaluated for effectiveness under contemporary scientific criteria, and no commitments to conduct the necessary effectiveness studies have been filed for them. The Commissioner therefore concludes that sulfanitran-antibacterial and aklomide-antibacterial combinations are properly deleted from § 121.264 and § 558.35, respectively, and is revoking items a through d in the table of § 121.264(c) and paragraph (g) (5) through (8) of § 558.35.

15. E. R. Squibb & Sons, Inc., commented that the Commissioner incorrectly proposed to revoke the regulations in § 121.220(d) for use of nystatin in the feed of laying and growing chickens and growing turkeys at 50 and 100 grams per ton. Squibb contended that the drug is an antifungal agent and thus beyond the scope of § 558.15.

The Commissioner agrees with this comment. The FDA Task Force on the Use of Antibiotics in Animal Feeds did not review antifungal products and made no recommendations concerning them. The Commissioner concludes that nystatin also has no significant effect on bacteria and viruses and is outside the purview of § 558.15. Therefore, he is vacating the proposed revocation of items 1, 2, and 3 in table 1 of § 121.220(d) for the use of nystatin as a single ingredient for growth promotion.

However, the nystatin-antibacterial combinations used for subtherapeutic purposes are within the scope of § 558.15. These combinations were not approved on the basis of contemporary effectiveness criteria, and no commitments were filed to conduct the requisite effectiveness studies. Therefore, the Commissioner concludes that all nystatin-antibacterial combinations are properly deleted from § 121.220(d).

16. Dow Chemical Company objected to the deletion of § 558.175(e)(1)(iii) (formerly § 135e.46(e), item 6. a and c) from the regulations, which covers clopidol (0.0125%), roxarsone (0.005%), and bacitracin methylene disalicylate (4 to 25 grams per ton); and clopidol (0.0125%), roxarsone (0.005%), and zinc bacitracin (4 to 25 grams per ton). The firm contended that these drug combinations had been evaluated and approved based on contemporary scientific criteria, and they are, therefore, outside the scope of § 558.15.

The Commissioner agrees with this comment. The NADA's for these new animal drugs were approved specifically for use in poultry feeds on the basis of contemporary effectiveness criteria, and studies are being conducted pursuant to § 558.15 to resolve the safety issues concerning the antibacterial components of these combinations. The Commissioner concludes that these drug combinations may be marketed when they are prepared from a drug listed in § 558.15(g)(1). Therefore, he is vacating the proposed deletion of these drug combinations from § 558.175.

17. The Diamond Shamrock Chemical Company questioned its omission from the list of approved sponsors in § 558.15(g)(2), asserting that it is participating in cooperative studies to resolve the safety of bacitracin methylene disalicylate as required by § 558.15, and that it has submitted protocols for in vitro and in vivo studies conducted with bacitracin methylene disalicylate in accordance with the requirements set by § 558.15(b)(1). Additionally, Diamond Shamrock asserted that it has letters from the holders of NADA's for bacitracin methylene disalicylate authorizing it to use the safety and effectiveness data in their files.

The Commissioner has reviewed the material submitted by Diamond Shamrock and concludes that the firm has complied with the intent and critical elements of § 558.15 by sponsoring studies to resolve the safety issues for bacitracin methylene disalicylate in animal feed. Although Diamond Shamrock failed to make certain technical filings by the appropriate date, it has substantially complied with the requirements of the regulation. Diamond Shamrock has now completed the necessary filings, and the Commissioner has added Diamond Shamrock to the list of sponsors of antibacterial premixes for bacitracin methylene disalicylate in § 558.15(g)(1).

18. Diamond Shamrock also objected to its omission from § 558.15(g)(2) as a sponsor of a chlortetracycline-arsanilic acid drug combination for use in swine feed and the proposed deletion of this combination from § 510.515 because it is actively conducting studies to meet the criteria imposed by § 558.15 and has filed the appropriate applications.

The Commissioner agrees with this comment. Therefore, this chlortetracycline-arsanilic acid drug combination has been added to § 558.15(g)(2) with Diamond Shamrock as its sponsor. The proposed revocation of this drug combination is vacated, and it has been added to § 510.515(c)(11).

19. A comment by American Cyanamid Company particularized the following specific instances in which it contended chlortetracyline drug combinations were improperly proposed for revocation from the regulations:

(a) Section 121.208(d), table 1, 6(a) and § 121.210(c), 2.1, 2.2, 3.1 and 4.1

(b) Section 121.208(d), table 1, 6(d) and § 121.207(c), 2.1 and 3.1

(c) Section 121.208(d), table 1, 6(e) and § 121.262(c), 1.1

(d) Section 121.208(d), table 1, 11(c) and § 121.207(c), 2.1 and 3.1

(e) Section 121.208(d), table 1, 15(a) and § 121.210(c), 2.11(u)

(f) Section 121.208(d), table 1, 16 and § 558.195(g)(4) (formerly § 135e.51(g)2b.1)

(g) Section 121.225(d)(3)(v) (formerly § 121.225(f)(3)(v))

(h) Section 121.262(c), 1.24 and § 558.515(f)(1)(ii) (formerly § 135e.66(f)(2))

(i) Section 121.208(d), table 1, 17 and § 558.515(f)(1)(iii), (iv), and (v) (formerly § 135e.66(f)(3), (4) and (5))

(j) Section 510.515(b)(23) (formerly § 144.26(b)(23))

(k) Section 510.515(b)(34) (formerly § 144.26(b)(34))

(l) Section 510.515(b)(43) (formerly § 144.26(b)(43))

The Commissioner concurs with this comment. Items (a) through (f) relate to drug combinations containing therapeutic levels of chlortetracycline, and the drugs are indicated for therapeutic uses. Item (g) relates to increased rate of gain uses in lambs and growing sheep. Safety studies for chlortetracycline sponsored by American Cyanamid Company are underway and drug efficacy requirements for the product were satisfied by the National Academy of Sciences-National Research Council's Review. The claim proposed for revocation in item (h) does not involve antibacterials. These drug combinations are beyond the scope of § 558.15, and the Commissioner is vacating the proposed revocation of these drug combinations.

The effectiveness of the uses covered by items (i) through (l) was established on the basis of contemporary scientific criteria, and commitments to conduct studies pursuant to § 558.15 to resolve safety issues concerning chlortetracycline have been submitted. Therefore, the Commissioner concludes that these drug combinations may be marketed when manufactured from chlortetracycline premixes listed in § 558.15(g)(1), and he is vacating the proposed revocation of these drug combinations. These drugs have been listed in the appropriate regulations on the basis of the Commissioner's determination.

20. Hess and Clark, Division of Rhodia, Inc., objected to the proposed revocation of paragraph (g)(3) and (4) of § 558.195 (formerly § 135e.51) providing for decoquinate-zinc bacitracin and decoquinate-chlortetracycline combinations because these drug combinations are the subject of recent NADA approvals. Furthermore, the manufacturers of zinc bacitracin and chlortetracycline premixes have filed commitments to conduct studies pursuant to § 558.15 to resolve the safety issues concerning these antibiotics.

The Commissioner agrees with this comment. The data in the NADA's for these drug combinations were evaluated using contemporary efficacy criteria, and the Commissioner previously concluded that the data demonstrated the effectiveness of the combinations. In addition, commitments to conduct the investigations required to establish the safety of the zinc bacitracin and chlortetracycline ingredients in the combinations have been filed in accordance with § 558.15. These drug combinations may be marketed when prepared from zinc bacitracin or chlortetracycline premixes listed in § 558.15(g)(1). Therefore, the proposed revocation of these drug combinations from the regulations is vacated.

21. Abbott Laboratories and its erythromycin thiocyanate premix for use in cattle were omitted from § 558.15(g)(1). Abbott objected to this omission, and it also opposed the proposed revocation of 20 specific antibacterial drug combinations from §§ 121.207, 121.210, 121.253, 121.292, and 510.515.

The Commissioner concludes that Abbott filed a proper commitment to conduct studies pursuant to § 558.15 to demonstrate the safety of erythromycin thiocyanate as a growth promotant in cattle. The appropriate material was filed by Abbott when the company realized that commitments were necessary to demonstrate the safety of the drug in each species of animal for which the drug is sought to be marketed. Therefore, the Commissioner has added Abbott's erythromycin thiocyanate premix to § 558.15(g)(1), and he is vacating the proposed deletion of this drug from § 510.515.

Abbott filed suitable commitments to conduct studies to demonstrate the effectiveness of certain erythromycin drug combinations in accordance with § 558.15. Based on these commitments the Commissioner concludes that those erythromycin drug combinations are eligible for interim marketing. Therefore, he is vacating the proposed revocation of the combinations of erythromycin and zoalene with or without arsanilic acid and the combinations of erythromycin, amprolium, and arsanilic acid with or without ethopabate from §§ 121.207, 121.210, 121.253, and 121.292.

22. Abbott Laboratories also opposed the revocation of bacitracin, zoalene, and arsanilic acid drug combinations from § 121.207(c) subitems 2.4c, 3.4c and § 121.253(c) subitem 1.8d and chlortetracycline, bacitracin, arsanilic acid, and sodium arsanilate combinations from § 510.515.

The Commissioner has received no commitment from Abbott or any other drug sponsor to conduct appropriate studies in support of the safety and effectiveness of these drug combinations. Therefore, the Commissioner concludes that these regulations are properly revoked.

23. Pfizer, Inc., objected to the proposed deletion of penicillin-streptomycin drug combinations from § 121.256(d), table 1, and the failure of the proposed amendments to list all antibacterials and antibacterial drug combinations for which Pfizer has filed proper commitments to conduct safety and effectiveness studies, namely, oxytetracycline, penicillin, streptomycin, and penicillin and streptomycin drug combinations in § 558.15(g)(1) and (2).

The Commissioner has concluded that Pfizer has filed the proper commitments and is conducting the requisite studies to demonstrate the safety and effectiveness of these drug products. Therefore, the Commissioner is vacating the proposed deletion of the penicillin-strepto-

mycin drug combinations from § 121.256 (d), table 1, and has added the oxytetracycline, penicillin, streptomycin, and penicillin-streptomycin drugs with Pfizer as their sponsor to § 558.15(g) (1) and (2), respectively. The indications for use of these drugs have been amended to correspond to those permitted under prior approvals held for the products by Pfizer.

The Commissioner has carefully considered the environmental effects of this action and, because the action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the FDA environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343–351 (21 U.S.C. 360b, 371(a))) and under authority delegated to the Commissioner (21 CFR 2.120), Parts 121, 510, and 558 are amended as follows:

1. In § 121.200 by adding a new paragraph (d) to read as follows:

§ 121.200 Definitions and interpretations applicable to Subpart C.

* * * * *

(d) Regulations prescribing conditions under which antibiotic, nitrofuran and sulfonamide drugs may be safely used in animal feed shall not be construed to relieve such drugs from the provisions of § 558.15 of this chapter where applicable.

2. In § 121.207(c) by revising the table to read as follows:

§ 121.207 Zoalene.

* * * * *

(c) * * *

ZOALENE IN COMPLETE FEEDS FOR CHICKENS AND TURKEYS

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1.1 Zoalene	113.5–170.3 (0.0125%–0.01875%)			For turkeys grown for meat purposes only.	Prevention and control of coccidiosis.
1.2 Zoalene	113.5–170.3 (0.0125%–0.01875%)	Carbarsone (not U.S.P.).	277–340.5 (0.025%–0.0375%)	For turkeys grown for meat purposes only; feed continuously beginning 2 weeks before blackhead and coccidiosis are expected and continue as long as prevention of blackhead and prevention and control of coccidiosis is needed; withdraw 5 days before slaughter; as sole source of organic arsenic.	Prevention and control of coccidiosis; aid in the prevention of blackhead.
a.–c. [Reserved]					
d. Zoalene	113.5–170.3	Arsanilic acid	90 (0.01%)	For turkeys grown for meat purposes only; withdraw 5 days before slaughter; as sole source of organic arsenic.	Growth promotion and feed efficiency, improving pigmentation.
e. Zoalene	113.5–170.3	Sodium arsanilate.	90 (0.01%)	do	Do.
f. Zoalene	113.5–170.3	3-Nitro-4-hydroxyphenylarsonic acid.	22.7–45.4	§ 121.262, table 1, item 2.1.	§ 121.262, table 1, item 2.1.
2.1 Zoalene	113.5 (0.0125%)			For broiler chickens	Prevention and control of coccidiosis.
2.2 Zoalene	113.5 (0.0125%)	Arsanilic acid	90 (0.01%)	For broiler chickens; withdraw 5 days before slaughter; as sole source of organic arsenic.	Prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.
2.3 Zoalene	113.5 (0.0125%)	Sodium arsanilate.	90 (0.01%)	do	Do.
2.4 Zoalene	113.5 (0.0125%)	3-Nitro-4-hydroxyphenylarsonic acid.	22.7–45.4 (0.0025%–0.005%)	do	Do.
2.5–2.7 [Reserved]					
2.8 Zoalene	113.5 (0.0125%)	Lincomycin	2	For broiler chickens; do not feed to laying chickens; to be fed as the sole ration; as lincomycin hydrochloride monohydrate provided by No. 000009, see § 510.600(c) of this chapter; zoalene provided by No. 025700, see § 510.600(c) of this chapter.	Increase in rate of weight gain, improved feed efficiency, and as an aid in the prevention and control of coccidiosis.
a. 2.1, 2.3, or 2.4	113.5	Penicillin	2.4–50	For broiler chickens; as procaine penicillin.	Growth promotion and feed efficiency.
b. [Reserved]					
c. 2.1, 2.4	113.5	Bacitracin	4–50	For broiler chickens; as bacitracin methylene disalicylate, or zinc bacitracin.	Do.
d. [Reserved]					
e. 2.1	113.5	Chlortetracycline	100–200	For broiler chickens; as prescribed in § 121.208(d), table 1, item 6, as chlortetracycline hydrochloride.	As prescribed in § 121.208(d), table 1, item 6.

ZOALENE IN COMPLETE FEEDS FOR CHICKENS AND TURKEYS—Continued

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
f. 2.1	113.5	Bacitracin	100-500	For broiler chickens; as prescribed in § 121.233(d), table 1, item 6.1; as zinc bacitracin.	As prescribed in § 121.233(d), table 1, item 6.1.
g.-i. [Reserved]					
j. 2.1, 2.2	113.5	Erythromycin	4.6-18.5	For broiler chickens; as erythromycin thiocyanate.	Growth promotion and feed efficiency.
k.-n. [Reserved]					
o. 2.1, 2.2	113.5	do	92.5-185	§ 121.292(d), items 1.1, 2.1, 4.1.	§ 121.292(d), items 1.1, 2.1, 4.1.
3.1 Zoalene	36.3-113.5 (0.004%-0.0125%)			For replacement chickens; in complete feed only; (grower ration not to be fed to birds over 14 weeks of age), as follows:	Development of active immunity to coccidiosis.

Growing conditions	Amount of zoalene in feed for birds by age group	
	Starter ration	Grower ration
	Grams per ton	*Grams per ton*
Severe exposure	113.5 (0.0125%)	75.4-113.5 (0.0083%-0.0125%)
Light to moderate exposure	75.4-113.5 (0.0083%-0.0125%)	36.3-75.4 (0.004%-0.0085%)

3.2 Zoalene	36.3-113.5 (0.004%-0.0125%)	Arsanilic acid	90 (0.01%)	For replacement chickens; in complete feed only; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic, as follows:	Development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.

Growing conditions	Starter ration	Grower ration
	Grams per ton	*Grams per ton*
Severe exposure	113.5 (0.0125%)	75.4-113.5 (0.0083%-0.0125%)
Light to moderate exposure	75.4-113.5 (0.0083%-0.0125%)	36.3-75.4 (0.004%-0.0085%)

3.3 Zoalene	36.3-113.5 (0.004%-0.0125%)	Sodium arsanilate	90 (0.01%)	For replacement chickens; in complete feed only; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic, as follows:	Development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.

Growing conditions	Starter ration	Grower ration
	Grams per ton	*Grams per ton*
Severe exposure	113.5 (0.0125%)	75.4-113.5 (0.0083%-0.0125%)
Light to moderate exposure	75.4-113.5 (0.0083%-0.0125%)	36.3-75.4 (0.004%-0.0085%)

ZOALENE IN COMPLETE FEEDS FOR CHICKENS AND TURKEYS—Continued

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
3.4 Zoalene	36.3–113.5 (0.004%–0.0125%)	3-Nitro-4-hydroxyphenylarsonic acid.	22.7–45.4 (0.0025%–0.005%)	For replacement chickens; in complete feed only; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic, as follows:	Development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.

Growing conditions	Starter ration	Grower ration
	Grams per ton	*Grams per ton*
Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0085%)

a. 3.1, 3.2, or 3.4	36.3–113.5 (0.004%–0.0125%)	Penicillin	2.4–50	Replacement chickens; as procaine penicillin.	Growth promotion and feed efficiency.
b.–d. [Reserved]					
e. 3.1	36.3–113.5 (0.004%–0.0125%)	Chlortetracycline	100–200	Replacement chickens; as prescribed in § 121.208(d), table 1, items 6 and 11, as chlortetracycline hydrochloride.	As prescribed in § 121.208(d), table 1, items 6 and 11.
f. 3.1	36.3–113.5	Bacitracin	100–500	For replacement chickens; as prescribed in § 121.233 (d), table 1, item 6.1; as zinc bacitracin.	As prescribed in § 121.233(d), table 1, item 6.1.
g.–i. [Reserved]					
j. 3.1, 3.2	36.3–113.5	Erythromycin	4.6–18.5	For replacement chickens; as erythromycin thiocyanate.	Growth promotion and feed efficiency.
k.–n. [Reserved]					
o. 3.1, 3.2	36.3–113.5	do	92.5–185	§ 121.292(d), table, items 1.1, 1.2, 2.1, 2.2, 4.1, 4.2.	§ 121.292(d), table, items 1.1, 1.2, 2.1, 2.2, 4.1, 4.2.

* * * * *

§ 121.208 [Amended]

3. In § 121.208 *Chlortetracycline* paragraph (d) is amended:

a. In table 1 by deleting subitems a through e following item 2; by deleting subitems a and b following item 3; by deleting subitem a following item 4; by deleting subitems a through c following item 5; by deleting subitems a and b following item 7; and by deleting the present text in subitem a following item 11 and designating the subitem "[Reserved]".

b. In table 2 by deleting subitem a following item 1.

4. In § 121.210(c) by revising the table to read as follows:

§ 121.210 Amprolium.

* * * * *

(c) * * *

TABLE 1—AMPROLIUM IN COMPLETE CHICKEN AND TURKEY FEED

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1.1 Amprolium	113.5–227 (0.0125%–0.025%)			For turkeys	Prevention of coccidiosis.
a. 1.1	113.5–227	Penicillin	2.4–50	For turkeys; as procaine penicillin.	Growth promotion and feed efficiency.
b.–d. [Reserved]					
e. 1.1	113.5–227	Bacitracin	4–50	For turkeys; as bacitracin methylene disalicylate.	Do.
f. [Reserved]					
g. 1.1	113.5–227	Penicillin plus streptomycin.	90–180	For turkeys; § 121.256(d), table 1, item 7.1.	§ 121.256(d), table 1, item 7.1.
h. [Reserved]					
i. 1.1	113.5–227	Arsanilic acid	90 (0.01%)	For turkeys; withdraw 5 days before slaughter; as sole source of organic arsenic.	Growth promotion and feed efficiency; improving pigmentation.
j. 1.1	113.5–227	Sodium arsanilate	90 (0.01%)	For turkeys; withdraw 5 days before slaughter.	Do.
k. 1.1	113.5–227	3-Nitro-4-hydroxyphenylarsonic acid.	22.7–45.4	§ 121.262, table 1, item 2.1.	§ 121.262, table 1, item 2.1.
l. 1.1	113.5–227	Bacitracin	100–500	§ 121.233(d), table 1, item 8.1.	§ 121.233(d), table 1, item 8.1.
m. 1.1	113.5–227	Penicillin plus bacitracin.	100–500	§ 121.233(d), table 1, item 8.2.	§ 121.233(d), table 1, item 8.2.
2.1 Amprolium	113.5–227 (0.0125%–0.025%)			For broiler chickens; for replacement chickens where immunity to coccidiosis is not desired.	Prevention of coccidiosis.
2.2 Amprolium	113.5–227 (0.0125%–0.025%)	Ethopabate	3.6 (0.0004%)	For broiler chickens; for replacement chickens where immunity to coccidiosis is not desired; not for laying hens.	Do.
2.3 Amprolium	113.5–227 (0.0125%–0.025%)	Arsanilic acid	90 (0.01%)	For broiler chickens; for replacement chickens where immunity to coccidiosis is not desired; as sole source of organic arsenic; withdraw 5 days before slaughter.	Prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.
2.4 Amprolium	113.5–227 (0.0125%–0.025%)	Ethopabate + Arsanilic acid	3.6 (0.0004%) 90 (0.01%)	For broiler chickens; for replacement chickens where immunity to coccidiosis is not desired; as sole source of organic arsenic; withdraw 5 days before slaughter; not for laying hens.	Do.
2.5–2.7 [Reserved]					
2.8 Amprolium	113.5–227 (0.0125%–0.025%)	3-Nitro-4-hydroxyphenylarsonic acid.	22.7–45.4 (0.0025%–0.005%)	For broiler chickens; for replacement chickens where immunity to coccidiosis is not desired; as sole source of organic arsenic; withdraw 5 days before slaughter.	Do.
2.9 Amprolium	113.5–227 (0.0125%–0.025%)	Ethopabate + 3-Nitro-4-hydroxyphenylarsonic acid.	3.6 (0.0004%) 22.7–45.4 (0.0025%–0.005%)	For broiler chickens; for replacement chickens where immunity to coccidiosis is not desired; as sole source of organic arsenic; withdraw 5 days before slaughter; not for laying hens.	Do.
2.10 Amprolium	113.5 (0.0125%)	Ethopabate + 3-Nitro-4-hydroxyphenylarsonic acid + Lincomycin	3.6 (0.0004%) 45.4 (0.005%) 2–4	For broiler chickens; not for laying chickens; as lincomycin hydrochloride monohydrate; withdraw 5 days before slaughter; as sole source of amprolium and organic arsenic.	For increase in rate of weight gain; improved feed efficiency and pigmentation; as an aid in the prevention of coccidiosis in broiler chickens.
2.11 Amprolium	113.5 (0.0125%)	Ethopabate + Lincomycin	3.6 (0.0004%) 2–4	For broiler chickens; not for laying chickens; as lincomycin hydrochloride monohydrate; as sole source of amprolium.	For increase in rate of weight gain; improved feed efficiency; as an aid in the prevention of coccidiosis in broiler chickens.

TABLE 1—AMPROLIUM IN COMPLETE CHICKEN AND TURKEY FEED—Continued

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
2.12 Amprolium	113.5 (0.0125%)	Bambermycins + Ethopabate	2-3 + 30.3 (0.004%)	For broiler chickens; feed continuously as the sole ration; as sole source of amprolium; amprolium, ethopabate as provided by No. 000906 in § 510.600 (c) of this chapter, bambermycins as provided by No. 000039 in § 510.600(c) of this chapter.	As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *E. acervulina*, *E. maxima*, and *E. brunetti* is likely to occur. For increased rate of weight gain, and improved feed efficiency.
2.13 Amprolium	113.5 (0.0125%)	Bambermycins + Ethopabate + Roxarsone	2-3 + 30.3 (0.004%) + 22.8-34.1 (0.0025%-0.00375%)	For broiler chickens; feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium and ethopabate as provided by No. 000906 in § 510.600(c) of this chapter, roxarsone by No. 017210, bambermycins by No. 000039. Withdraw 5 days before slaughter.	As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *E. acervulina*, *E. maxima*, and *E. brunetti* is likely to occur. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.
2.14 Amprolium	113.5 (0.0125%)	Bambermycins + Ethopabate + Roxarsone	2-3 + 3.03 (0.0004%) + 22.8-34.1 (0.0025%-0.00375%)	do	As an aid in the prevention of coccidiosis. For increased rate of weight gain, improved feed efficiency and improved pigmentation.
2.15 Amprolium	113.5 (0.0125%)	Bambermycins + Roxarsone	2-3 + 22.8-34.1 (0.0025%-0.00375%)	For broiler chickens; feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium as provided by No. 000906 in § 510.600(c) of this chapter, roxarsone by No. 017210, bambermycins by No. 000039. Withdraw 5 days before slaughter.	Do.
a. 2.1, 2.2	113.5-227	Penicillin	2.4-50	As procaine penicillin	Growth promotion and feed efficiency.
b.-d. [Reserved]					
e. 2.1, 2.2, or 2.9	113.5-227	Bacitracin	4-50	As bacitracin methylene disalicylate.	Do.
f.-g. [Reserved]					
h. 2.1 or 2.2	113.5-227	Bacitracin	100-200	As bacitracin methylene disalicylate.	Treatment of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).
i. 2.1 or 2.2	113.5-227	Chlortetracycline	100-200	As prescribed in § 121.208(d), table 1, item 6.	§ 121.208(d), table 1, item 6.
j. 2.1 or 2.2	113.5-227	Penicillin plus streptomycin	90-180	§ 121.256(d), table 1, item 5.1.	§ 121.256(d), table 1, item 5.1.
k.-m. [Reserved]					
n. 2.1	113.5-227	Sodium arsanilate	90 (0.01%)	§ 121.254(c), table, item 1.	Growth promotion and feed efficiency; improving pigmentation.
o.-r. [Reserved]					
s. 2.1, 2.2, 2.3, and 2.4	113.5-227	Erythromycin	4.6-18.5	As erythromycin thiocyanate.	Growth promotion and feed efficiency.
t. 2.1, 2.2, 2.3, and 2.4	113.5-227	do	92.5-185	§ 121.292(d), table, items 1.1, 1.2, 2.1, 2.2, 4.1, and 4.2.	§ 121.292(d), table; items 1.1, 1.2, 2.1, 2.2, 4.1, and 4.2.
u. 2.2		Chlortetracycline	300	For broiler chickens; in low calcium feed containing 0.8 percent dietary calcium and 1.5 percent sodium Sulfate; feed continuously as sole ration for not more than the first 3 weeks of life.	Treatment of chronic respiratory disease caused by strains of *Mycoplasma gallisepticum* susceptible to chlortetracycline.
v. 2.1 or 2.2	113.5-227	Bacitracin	100-200	§ 121.233(d), table 1, item 6.1.	§ 121.233(d), table 1, item 6.1.

TABLE 1—ANTICOCCIDIA IN COMPLETE CHICKEN AND TURKEY FEED—Continued

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
3.1 Amprolium	36.3–113.5 (0.004%–0.0125%)			For replacement chickens; as follows:	Development of active immunity to coccidiosis.

Growing conditions	Amount of amprolium in feed for birds by age groups		
	Up to 5 weeks of age	From 5 to 8 weeks of age	Over 8 weeks of age
	Grams per ton	*Grams per ton*	*Grams per ton*
Severe exposure to coccidiosis.	113.5 (0.0125%)	72.6–113.5 (0.008%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Moderate exposure to coccidiosis.	72.6–113.5 (0.008%–0.0125%)	54.5–113.5 (0.006%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Slight exposure to coccidiosis.	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)

3.2 Amprolium	36.3–113.5 (0.004%–0.0125%)	Arsanilic acid	90 (0.01%)	For replacement chickens; as specified in item 3.1 of this table; withdraw 5 days before slaughter; as sole source of organic arsenic.	Development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.
3.3 Amprolium	36.3–113.5 (0.004%–0.0125%)	Sodium arsanilate	90 (0.01%)	do	Do.
a. 3.1 or 3.2	36.3–113.5	Penicillin	2.4–50	As procaine penicillin	Growth promotion and feed efficiency.
b.–g. [Reserved]					
h. 3.1	36.3–113.5	Bacitracin	100–200	As bacitracin, bacitracin methylene disalicylate, or zinc bacitracin.	Treatment of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).
i. 3.1	36.3–113.5	Chlortetracycline	100–200	As prescribed in § 121.208(d), table 1, item 6.	§ 121.208(d), table 1, item 6.
j. 3.1	36.3–113.5	Penicillin plus streptomycin	50–100	§ 121.256(d), table 1, item 5.1.	§ 121.256(d), table 1, item 5.1.
k.–l. [Reserved]					
m. 3.1, 3.2	36.3–113.5	Erythromycin	4.6–18.5	As erythromycin thiocyanate.	Growth promotion and feed efficiency.
n. 3.1, 3.2	36.3–113.5	do	92.5–185	§ 121.292(d), table, items 1.1, 1.2, 2.1, 2.2, 4.1, 4.2.	§ 121.292(d), table, items 1.1, 1.2, 2.1, 2.2, 4.1, 4.2.
o.–p. [Reserved]					
q. 3.1	36.3–113.5	3-Nitro-4-hydroxy-phenylarsonic acid	22.7–45.4	§ 121.262, table 1, item 1.1.	§ 121.262, table 1, item 1.1.
r.–s. [Reserved]					
4.1 Amprolium	72.6–113.5 (0.008%–0.0125%)			For broiler chickens	Prevention of coccidiosis caused by *E. tenella* only.
4.2 Amprolium	72.6–113.5 (0.008%–0.0125%)	Arsanilic acid	90 (0.01%)	For broiler chickens; withdraw 5 days before slaughter; as sole source of organic arsenic.	Prevention of coccidiosis caused by *E. tenella* only; growth promotion and feed efficiency; improving pigmentation.
4.3 Amprolium	72.6–113.5 (0.008%–0.0125%)	3-Nitro-4-hydroxy-phenylarsonic acid	22.7–45.4 (0.0025%–0.005%)	do	Do.
a. 4.1	72.6–113.5	Penicillin	2.4–50	As procaine penicillin	Growth promotion and feed efficiency.
b.–g. [Reserved]					
h. 4.1	72.6–113.5	Bacitracin	100–200	As bacitracin methylene disalicylate, or zinc bacitracin.	Treatment of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).
i. 4.1	72.6–113.5	Chlortetracycline	100–200	As prescribed in § 121.208(d), table 1, item 6.	§ 121.208(d), table 1, item 6.
j. 4.1	72.6–113.5	Penicillin plus streptomycin	50–100	§ 121.256(d), table 1, item 5.1.	§ 121.256(d), table 1, item 5.1.
k.–m. [Reserved]					
n. 4.1	72.6–113.5	Sodium arsanilate	90	Withdraw 5 days before slaughter; as sole source of organic arsenic.	Growth promotion and feed efficiency; improving pigmentation.
5.1 Amprolium	113.5 (0.0125%)			For moderate outbreaks of coccidiosis in laying chickens; administer for 2 weeks.	Treatment of coccidiosis.
6.1 Amprolium	227 (0.025%)			For severe outbreaks of coccidiosis in laying chickens; administer for 2 weeks.	Do.

TABLE 1—AMPROLIUM IN COMPLETE CHICKEN AND TURKEY FEED—Continued

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
7.1 Amprolium	113.5 (0.0125%)	Ethopabate	28.3 (0.004%)	For broiler chickens; for replacement chickens where immunity to coccidiosis is not desired; not for chickens over 16 weeks of age.	As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *E. acervulina*, *E. maxima*, and *E. brunetti* is likely to occur.
a. 7.1		Bacitracin	4–50	For broiler chickens; do not feed to laying chickens; as sole source of amprolium; not for use as a treatment for outbreaks of coccidiosis; as bacitracin methylene disalicylate as provided by code No. 000794 in § 510.600(c) of this chapter; feed as the sole ration from the time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; approval for this combination granted to firm No. 000006 as identified in § 510.600(c) of this chapter.	To aid in prevention of coccidiosis where severe exposure to coccidiosis from *E. acervulina*, *E. maxima*, and *E. brunetti* is likely to occur; for increased rate of weight gain in broiler chickens raised in floor pens.
b. 7.1		3-Nitro-4-hydroxyphenylarsonic acid.	45.4 (0.005%)	For broiler chickens; do not feed to laying chickens; withdraw 5 days before slaughter; as sole source of amprolium; do not use as a treatment for outbreaks of coccidiosis; feed as the sole ration from time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; 3-nitro - 4 - hydroxyphenylarsonic acid as provided by code No. 017210 in § 510.600(c) of this chapter; approval for this combination granted to firm No. 000006 as identified in § 510.600(c) of this chapter.	Do.
8.1 Amprolium	113.5 (0.0125%)			For laying chickens	Prevention of coccidiosis.
9.1 Amprolium	113.5 (0.0125%)	3-Nitro-4-hydroxyphenylarsonic acid.	34 (0.00375%)	For floor raised broiler chickens; do not feed to laying chickens; withdraw 5 days before slaughter; as sole source of amprolium and organic arsenic; as bacitracin methylene disalicylate; do not use as a treatment for outbreaks of coccidiosis; feed as the sole ration from time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; amprolium and ethopabate as provided by code No. 000006 in § 510.600(c) of this chapter; bacitracin methylene disalicylate as provided by code No. 000794 in § 510.600(c) of this chapter; 3-nitro-4-hydroxyphenylarsonic acid as provided by code No. 017210 in § 510.600(c) of this chapter; approval for this combination granted to firm No. 000006 as identified in § 510.600 (c) of this chapter.	For increased rate of weight gain and as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *E. acervulina*, *E. maxima*, and *E. brunetti* is likely to occur in broiler chickens raised in floor pens.
		+ Ethopabate	28.3 (0.004%)		
		+ Bacitracin	5–35		

TABLE 1—AMPROLIUM IN COMPLETE CHICKEN AND TURKEY FEED—Continued

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
10.1 Amprolium	113.5 (0.0125%)	3-Nitro-4-hydroxyphenylarsonic acid. + Ethopabate + Bacitracin methylene disalicylate.	34 (0.0037%) 20.5 (0.0045%) 20-50	do	For increased rate of weight gain, improved feed efficiency, and as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *E. acervulina*, *E. maxima*, and *E. tenella* is likely to occur in broiler chickens raised in floor pens.

* * * * *

5. In § 121.213(d) by revising tables 1 and 2 to read as follows:

§ 121.213 Hygromycin B.

* * * * *

(d) * * *

TABLE 1—HYGROMYCIN B IN COMPLETE CHICKEN FEED

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1. Hygromycin B	8-12				Control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*).
a.–g. [Reserved]					
h. Hygromycin B	8-12	Penicillin	100	§ 121.256(d), table 1, item 9.1.	§ 121.256(d), table 1, item 9.1.
i. Hygromycin B	8-12	Penicillin plus bacitracin.	100-500	§ 121.256(d), table 1, items 11.1, 16.1.	§ 121.256(d), table 1, items 11.1, 16.1.
j. Hygromycin B	8-12	Penicillin plus streptomycin.	50-100	§ 121.256(d), table 1, item 8.1.	§ 121.256(d), table 1, item 8.1.
k. [Reserved]					
l. Hygromycin B	8-12	Bacitracin	100	As bacitracin methylene disalicylate, or zinc bacitracin.	Treatment of chronic respiratory disease (air-sac infection), blue comb (non-specific infectious enteritis).
m. [Reserved]					
n. Hygromycin B	8-12	Chlortetracycline	100-500	§ 121.208(d), table 1, item 6.	§ 121.208(d), table 1, item 6.

TABLE 2—HYGROMYCIN B IN COMPLETE SWINE FEED

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1. Hygromycin B	12			For swine; withdraw 48 hours before slaughter.	Control of infestation of large roundworms (*Ascaris suis*), nodular worms (*Oesophagostomum dentatum*), and whipworms (*Trichuris suis*).
a.–b. [Reserved]					
c. Hygromycin B	12	Chlortetracycline	100-200	For swine; as chlortetracycline hydrochloride; withdraw 48 hours before slaughter.	Treatment of bacterial swine enteritis.

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§ 121.220 [Amended]

6. In § 121.220 *Nystatin*, paragraph (d) is amended in the table by deleting subitems a through f following items 1, 3, 4, and 6.

7. By revising § 121.225 to read as follows:

§ 121.225 Antibiotics for growth promotion and feed efficiency.

The antibiotics listed in this section may be safely used in animal feeds as an aid in stimulating growth and improving feed efficiency, in accordance with the following prescribed conditions:

(a) *Procaine penicillin.* Procaine penicillin as follows:

(1) Procaine penicillin is the procaine salt of the antibiotic substance produced by the growth of *Penicillium notatum* or *Penicillium chrysogenum* or the same antibiotic substances produced by any other means.

(2) The quantities of the antibiotics referred to in this paragraph refer to activities equivalent to those of the appropriate antibiotic master standards.

(3) It is used or intended for use:

(i) In the feed of chickens, turkeys, and pheasants in an amount not less than 2.4 grams nor more than 50 grams per ton of finished feed.

(ii) In the feed of quail not over 5 weeks of age, in an amount not less than 5 grams nor more than 20 grams per ton of finished feed.

(iii) With streptomycin in the feed of chickens and turkeys at a level of 2.4 to 7.5 grams per ton of procaine penicillin with 12.0 to 37.5 grams per ton of streptomycin and in the feed of chickens at a level of 3.75 to 7.5 grams per ton of penicillin and 18.75 to 37.5 grams per ton of streptomycin.

(iv) With streptomycin in the feed of swine at a level of 1.5 to 7.5 grams per ton of penicillin combined with 7.5 to 37.5 grams per ton of streptomycin in the finished feed.

(v) In the feed of swine in an amount not less than 10 grams of penicillin nor more than 50 grams penicillin per ton of finished feed.

(b) *Zinc bacitracin.* Zinc bacitracin as follows:

(1) Zinc bacitracin is the zinc salt of the antibiotic substance produced by growth of *Bacillus subtilis* var. Tracy or the same antibiotic substance produced by any other means, and for the purposes of this paragraph refers to zinc bacitracin or feed grade zinc bacitracin.

(2) The quantities of the antibiotics referred to in this paragraph refer to activities equivalent to those of the appropriate antibiotic master standards.

(3) It is used or intended for use:

(i) In the feed of chickens, turkeys, and pheasants in an amount not less than 4 grams nor more than 50 grams per ton of finished feed.

(ii) In feed for growing cattle, in an amount providing not less than 35 milligrams nor more than 70 milligrams per animal per day.

(iii) In the feed of quail not over 5 weeks of age, in an amount not less than 5 grams nor more than 20 grams per ton of finished feed.

(iv) In the feed of swine, in an amount not less than 10 grams nor more than 50 grams per ton of finished feed.

(c) *Bacitracin methylene disalicylate.* Bacitracin methylene disalicylate as follows:

(1) Bacitracin methylene disalicylate is the methylene disalicylate salt of the antibiotic substance produced by growth of *Bacillus subtilis* var. Tracy or the same antibiotic substance produced by any other means, and for the purpose of this paragraph refers to bacitracin methylene disalicylate or feed grade bacitracin methylene disalicylate.

(2) The quantities of the antibiotics referred to in this paragraph refer to activities equivalent to those of the appropriate antibiotic master standards.

(3) It is used or intended for use:

(i) In the feed of chickens and turkeys in an amount not less than 4 grams nor more than 50 grams per ton of finished feed.

(ii) In the feed of swine, in an amount not less than 10 grams nor more than 50 grams per ton of finished feed.

(d) *Chlortetracycline.* Chlortetracycline as follows:

(1) Chlortetracycline is the antibiotic substance produced by growth of *Streptomyces aureofaciens* or the same antibiotic substance produced by any other means, and for the purposes of this paragraph refers to chlortetracycline or feed grade chlortetracycline.

(2) The quantities of the antibiotic referred to in this paragraph refer to activity equivalent to that of the appropriate antibiotic master standard.

(3) It is used or intended for use:

(i) In the feed of chickens and turkeys, in an amount not less than 10 grams nor more than 50 grams per ton of finished feed.

(ii) In the feed of mink, in an amount not less than 20 grams nor more than 50 grams per ton of finished feed and also as an aid in increasing pelt size.

(iii) In the feed of horses up to 1 year of age in the amount of 85 milligrams per head per day, where such horses are not to be slaughtered for food purposes.

(iv) In the feed of swine, in an amount not less than 10 grams nor more than 50 grams per ton of finished feed.

(v) In the feed of lambs and growing sheep, in an amount not less than 20 grams nor more than 50 grams per ton of finished feed.

(vi) In the feed of calves, in an amount not less than 25 milligrams per head per day nor more than 70 milligrams per head per day in finished feed.

(vii) In the feed of growing cattle, in an amount equal to 70 milligrams per head per day in finished feed.

(viii) In the feed of calves up to 250 pounds in weight, in an amount providing 0.1 milligram per pound of body weight per day in milk replacers or starter feeds.

(e) *Erythromycin thiocyanate.* Erythromycin thiocyanate as follows:

(1) Erythromycin thiocyanate is the thiocyanate salt of the antibiotic substance produced by the growth of *Streptomyces erythreus* or the same antibiotic substance produced by any other means.

(2) The levels of antibiotics listed are expressed in terms of the weight of erythromycin master standard. One gram of erythromycin thiocyanate is equivalent to 0.925 gram of erythromycin master standard.

(3) It is used or intended for use:

(i) In the feed of chickens, in an amount not less than 4.6 grams nor more than 18.5 grams per ton of finished feed.

(ii) In the feed of turkeys not over 12 weeks of age, in an amount not less than 9.25 nor more than 18.5 grams per ton of finished feed.

(iii) In the feed of feedlot beef cattle at 37 milligrams per head per day.

(f)–(v) [Reserved]

(w) *Labeling requirements.* (1) To assure safe use, the label and labeling of the additive, any combination of additives, and any feed additive supplement, feed additive concentrate, or feed additive premix prepared therefrom, shall bear, in addition to the other information required by the act, the following:

(i) The name of the additive or additives.

(ii) A statement of the quantity of each contained in any mixtures.

(iii) A statement of the conditions for which the feed is to be used.

(iv) Adequate mixing directions to provide a complete feed with the proper concentration of the additive or additives, whether or not intermediate feed additive supplements, feed additive concentrates, or feed additive premixes are also used.

NOTE: § 121.225(w) was amended by an order published in the FEDERAL REGISTER on March 20, 1965, 30 FR 3708, effective January 1, 1966, and was stayed at 30 FR 12353, September 28, 1965.

§ 121.232 [Reserved]

8. By revoking § 121.232 *Bacitracin* and reserving it for future use.

9. In § 121.233(d) by revising tables 1 and 2 to read as follows:

§ 121.233 Zinc bacitracin.

• • • • •

(d) • • •

TABLE 1—ZINC BACITRACIN IN COMPLETE CHICKEN AND TURKEY FEED

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1.1 Bacitracin	10–50			For chickens; 50 grams per ton first 4 to 6 weeks of egg production; 10–50 grams per ton for remainder of egg-laying period; as zinc bacitracin.	Maintaining or increasing egg production.
2.1 Bacitracin	50–100			For chickens; as zinc bacitracin.	Prevention of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis).
3.1 Bacitracin	50–100			For turkeys; as zinc bacitracin.	Prevention of infectious sinusitis, blue comb (mud fever).
4.1 Bacitracin	100			For chickens; as zinc bacitracin.	Maintaining or increasing hatchability of eggs.
5.1 Bacitracin	100			do	During times of stress, prevention of diseases named in this section caused by organisms susceptible to bacitracin.
6.1 Bacitracin	100–500			do	Treatment of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis).
6.2 Bacitracin plus penicillin.	100–500			For chickens; 100–500 grams of combination, containing not less than 50 percent nor more than 75 percent of bacitracin except that it contains not more than 125 grams of penicillin; as procaine penicillin plus zinc bacitracin.	Do.
a. 6.1	100–200	Amprolium	36.3–227	§ 121.210, table 1, items 2.1, 3.1, and 4.1.	§ 121.210, table 1, items 2.1, 3.1, and 4.1.
b. 6.1	100–200	Amprolium + ethopabate.	113.5–227 3.6	As prescribed in § 121.210(c), table 1, item 2.2.	§ 121.210 (c), table 1, item 2.2.
c. 6.1	100	Hygromycin B	8–12	For chickens	§ 121.213(d), table 1, item 1.
d. 6.2	100	do	8–12	For chickens; 100 grams of combination; not less than 25 grams of penicillin nor less than 50 grams of bacitracin.	Do.
e. 6.1	100–200	Zoalene	36.3–113.5	For chickens; not for laying chickens; as prescribed in § 121.207(c), table, items 2.1 and 3.1.	§ 121.207(c), table, items 2.1 and 3.1.
7.1 Bacitracin	100–500			For chicks; in starter ration; as zinc bacitracin.	Prevention of early mortality of chicks due to organisms susceptible to zinc bacitracin.
8.1 Bacitracin	100–500			For turkeys; as zinc bacitracin.	Treatment of infectious sinusitis, blue comb (mud fever).
8.2 Bacitracin plus penicillin.	100–500			For turkeys; 100–500 grams of combination, containing not less than 50 percent nor more than 75 percent of bacitracin except that it contains not more than 125 grams of penicillin; as procaine penicillin plus zinc bacitracin.	Do.
a. 8.1, 8.2	100–200	Amprolium	113.5–227	For turkeys; as prescribed in § 121.210(c), table 1, item 1.1.	§ 121.210(c), table 1, item 1.1.

TABLE 2—ZINC BACITRACIN IN COMPLETE SWINE FEED

1.1 Bacitracin	50–100			For swine; as zinc bacitracin.	Aid in the prevention of bacterial swine enteritis.
2.1 Bacitracin	100			do	Treatment of bacterial swine enteritis.
2.2 Bacitracin plus penicillin.	100			For swine; 100 grams of combination, containing not less than 50 percent nor more than 75 percent of bacitracin; as zinc bacitracin plus procaine penicillin.	Do.

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10. In § 121.237(d) by revising the table to read as follows:

§ 121.237 Nihydrazone.

* * * * *

(d) * * *

NIHYDRAZONE IN COMPLETE CHICKEN FEED

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1. Nihydrazone	100			For broilers; for replacement chickens not over 14 weeks of age; not for laying chickens.	Prevention of chronic respiratory disease (air-sac infection). In the presence of chronic respiratory disease (air-sac infection) to reduce mortality and severity of infection, to reduce the number of lesions, and assist in maintaining weight gains and feed efficiency. Prevention of pullorum disease; fowl typhoid; paratyphoid (salmonellosis) coccidiosis caused by *E. tenella*, *E. necatrix*, *E. maxima*, and *E. brunetti* and histomoniasis (blackhead).
a. Nihydrazone	100	Penicillin	2.4–50	As procaine penicillin	Growth promotion and feed efficiency.
b. [Reserved]					
c. Nihydrazone	100	Bacitracin	4–50	As bacitracin methylene disalicylate, or zinc bacitracin.	Growth promotion and feed efficiency.
d. Nihydrazone	100	Chlortetracycline	10–50	As chlortetracycline hydrochloride.	Do.

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§ 121.251 [Amended]

11. In § 121.251 *Oxytetracycline*, paragraph (d) is amended in table 1 by deleting subitems a through c following items 3 and 6.

§ 121.252 [Amended]

12. In § 121.252 *Bacitracin methylene disalicylate*, paragraph (d) is amended as follows:

a. In table 1 by deleting the following items and subitems: Item 1.2 and subitem a; item 2.2 and subitems a through d; item 3.2 and subitem a; item 5.2 and subitem a; item 6.2 and subitem a; subitems a through c following item 7.2; and item 4.2 and subitem a.

b. In table 2 by deleting item 1.2.

§ 121.253 [Amended]

13. In § 121.253 *Arsanilic acid*, paragraph (c) is amended in the table by deleting subitems a through e following item 1.3 and designating the subitems as "[Reserved]."

§ 121.256 [Amended]

14. In § 121.256 *Penicillin*, paragraph (d) is amended as follows:

a. In table 1 by deleting the following items and subitems: Item 1.1 and subitem a; subitem a following item 2.1; item 3.2 and subitems a and b; item 4.2 and subitem a; item 6.1 and subitem a; subitems a through c following item 8.1; item 10.1 and subitem a; items 12.1, 13.1 and subitem a, 15.1.

b. In table 1 items 16.1 and 17.1 under the limitations column by deleting "bacitracin or" following the words "procaine penicillin +."

c. In table 2 by deleting item 1 and designating the item as [Reserved].

d. In table 2 item 3 under the limitations column by deleting the word "bacitracin," following "procaine penicillin +."

15. In § 121.262(c) the table is amended by deleting subitems a through k following items 1.18 and 2.2 and by adding new subitems j and k following item 1.18 and new subitem a following item 2.2 to read as follows:

§ 121.262 3-Nitro-4-hydroxyphenylarsonic acid.

* * * * *

(c) * * *

TABLE 1—3-NITRO-4-HYDROXYPHENYLARSONIC ACID IN COMPLETE CHICKEN AND TURKEY FEED

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
• • •	• • •	• • •	• • •	• • •	• • •
1.18 • • •					
a.–i. [Reserved]					
j. 1.3	22.7–45.4	Chlortetracycline.	100–200	§ 121.208, table 1, item 6	§ 121.208, table 1, item 6.
k. 1.3, 1.4	22.7–45.4	Bacitracin	4–50	As zinc bacitracin	Growth promotion and feed efficiency.
• • •	• • •	• • •	• • •	• • •	• • •
2.2 • • •					
a. 2.1	22.7–45.4	Chlortetracycline.	100–200	§ 121.208, table 1, item 7	§ 121.208, table 1, item 7.
b.–k. [Reserved]					

• • • • • •

§ 121.264 [Amended]

16. In § 121.264 *Sulfanitran (acetyl-(p-nitrophenyl)-sulfanilamide)* by revoking subitems a through d following item 1.5 in the table in paragraph (c).

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17. Section 510.515 is revised to read as follows:

§ 510.515 Animal feeds bearing or containing new animal drugs subject to the provisions of section 512(n) of the act.

Animal feeds that bear or contain penicillin, streptomycin in combination with penicillin, chlortetracycline, feed grade zinc bacitracin, and bacitracin methylene disalicylate, with or without added suitable nutritive ingredients are exempt from the certification requirements of section 512 of the act provided they are the subject of and in compliance with regulations for their use in Subpart C of Part 121 of this chapter, Part 558 of this chapter, or any one of the paragraphs of this section:

(a) Where indicated in paragraph (b) of this section it is manufactured with or without one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(1) Arsanilic acid: Not less than 0.005 percent and not more than 0.01 percent.

(2) Sodium arsanilate: Not less than 0.005 percent and not more than 0.01 percent.

(3) 3-Nitro-4-hydroxyphenylarsonic acid: Not less than 0.0025 percent and not more than 0.0075 percent except in chicken or turkey feed which shall contain not less than 0.0025 percent and not more than 0.005 percent.

(4) Furazolidone: 0.00083 percent.

(5) Furazolidone 0.00083 percent, with or without nitrofurazone 0.0056 percent, and/or 3-nitro-4-hydroxyphenylarsonic acid not less than 0.0025 percent and not more than 0.0075 percent except in chicken or turkey feed in which the limit of 3-nitro-4-hydroxyphenylarsonic acid shall be not less than 0.0025 percent and not more than 0.005 percent.

(b) It is intended for use in any one of the following conditions set forth in this paragraph:

(1)–(6) [Reserved]

(7) (i) It is intended for use solely as a treatment for complicated, chronic respiratory disease (air-sac infection), infectious sinusitis, blue comb (nonspecific infectious enteritis, mud fever), and hexamitiasis in poultry, and/or bacterial swine enteritis; its labeling contains adequate directions and warnings for such use; and it contains, per ton of feed, not less than 100 grams of chlortetracycline, or oxytetracycline, or a combination of such drugs, or not less than 90 grams nor more than 180 grams of penicillin and streptomycin in a combination containing 16.7 percent penicillin.

(a) When intended for the uses specified in this paragraph (b) (7) (i), it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section. If it is intended for use solely in poultry, it may contain 0.1 percent of para-aminobenzoic acid or the sodium or potassium salt of para-aminobenzoic acid.

(b) If it is intended for use solely in the treatment of the diseases of chickens described in this paragraph (b) (7) (i), it contains, per ton of feed, not less than 100 grams and not more than 200 grams of chlortetracycline and it contains not less than 0.4 percent and not more than 0.8 percent of dietary calcium, then representations may be made in its labeling to the effect that the reduced amount of calcium aids in increasing the concentrations of the antibiotic in the blood of treated birds; the labeling of such medicated feed shall include that required by § 121.208 of this chapter.

(c) If it is intended for use solely as a treatment for bacterial swine enteritis, it may contain, per ton of feed, not less than 90 grams nor more than 270 grams of penicillin and streptomycin in a combination containing 16.7 percent penicillin, provided that its labeling bears a warning that the feed is not to be used for more than 14 days.

(ii) [Reserved]

(iii) It is also intended for use in the treatment of coccidiosis in chickens caused by *E. tenella* and *E. necatrix;* its labeling bears adequate directions and warnings for such use (including the directions and warnings required by paragraph (b) (7) (i) of this section); and it contains, per ton of feed, 200 grams

of chlortetracycline and 0.4 percent to 0.55 percent of dietary calcium.

(8)–(9) [Reserved]

(10) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection), infectious sinusitis, and blue comb (nonspecific infectious enteritis) in poultry and/or bacterial swine enteritis; its labeling bears adequate directions and warnings for such use; and it contains, per ton of feed, the equivalent of either 100 grams of penicillin, or not less than 100 grams and not more than 500 grams of bacitracin (as zinc bacitracin), or not less than 100 grams and not more than 200 grams of bacitracin (as bacitracin methylene disalicylate), or not less than 100 grams and not more than 500 grams of penicillin and bacitracin (as zinc bacitracin) in a combination containing not less than 50 percent nor more than 75 percent of bacitracin but in no case containing more than 125 grams of penicillin, or not less than 100 grams and not more than 200 grams of penicillin and bacitracin (as bacitracin methylene disalicylate) in a combination containing not less than 25 percent of penicillin nor less than 50 percent of bacitracin; except that, if it is intended for the treatment of bacterial swine enteritis, it contains, per ton of feed, either 100 grams of bacitracin (as zinc bacitracin or bacitracin methylene disalicylate), or 100 grams of a combination of penicillin and bacitracin (as zinc bacitracin or bacitracin methylene disalicylate), containing not less than 50 percent nor more than 75 percent of bacitracin. When intended for the uses specified in this paragraph (b)(10), it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section; *Provided, however,* That the level of antibiotic or antibiotic combination present is not greater than the minimum amount specified therefor in this paragraph (b)(10).

(11) It is intended for use solely as a treatment for bacterial swine enteritis caused by *Salmonella choleraesuis,* its labeling bears adequate directions and warnings for such use, and it contains nitrofurazone in a quantity, by weight of feed, of 0.056 percent.

(12) [Reserved]

(13) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection) and infectious sinusitis in poultry; its labeling bears adequate directions and warnings for such use; and it contains not less than 0.1 percent para-aminobenzoic acid or the sodium or potassium salt or para-aminobenzoic acid.

(14) [Reserved]

(15) It is intended for use solely as an aid in the treatment of poultry in outbreaks of fowl typhoid, pullorum, the paratyphoids, infectious arthritis due to a filterable agent, histomoniasis (blackhead), hexamitiasis, quail disease (ulcerated enteritis), paracolon infection, avian infectious hepatitis, and coccidiosis, its labeling bears adequate directions and warnings for such use; and it contains the following quantities of furazolidone, by weight of feed, for the conditions indicated:

(i) For fowl typhoid, pullorum, and the paratyphoids in birds regardless of age: 0.011 percent.

(ii) For the treatment of histomoniasis (blackhead), paracolon infection, and avian infectious hepatitis of chickens, and to lessen the morbidity in outbreaks of infectious arthritis due to a filterable agent: 0.022 percent.

(16) [Reserved]

(17) (i) It is intended for use solely as an aid in the treatment of chronic respiratory disease (air-sac infection), infectious sinusitis, blue comb (nonspecific infectious enteritis, mud fever) in poultry; its labeling bears adequate directions and warnings for such use; and it contains not less than 100 grams of chlortetracycline or oxytetracycline or a combination of these two drugs per ton of feed. When intended for such use, it may also contain the equivalent of not less than 100 grams of bacitracin per ton of feed.

(ii) It is also intended for the treatment of the diseases of poultry specified in paragraph (b)(15) of this section; it contains one of the ingredients in the amount and under the conditions set forth in paragraph (b)(17)(i) of this section; and it contains furazolidone in the amount specified in paragraph (b)(15) of this section.

(18)–(24) [Reserved]

(25) It is a medicated cattle feed containing chlortetracycline in the amounts and for the purposes indicated in § 121.208 of this chapter, and its labeling bears adequate directions and warnings for such use.

(26) (i) It is intended for use solely for accelerating weight gains in beef cattle, and it contains a quantity of diethylstilbestrol adequate to provide not more than 10 milligrams per head per day when fed in accordance with the directions for use that accompany the feed, and there has been submitted to the Commissioner, in triplicate, adequate information of the kind required for Form FD–1800 and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approved supplement to the application provides for the change, or with change is made in conformance with other provisions of § 514.9 of this chapter.

(ii) It is also intended for the prevention or treatment of the diseases specified in paragraph (b)(25) of this section. It contains diethylstilbestrol in the amount and under the conditions set forth in paragraph (b)(26)(i) of this section, and it contains the antibiotic in the amount specified in paragraph (b)(25) of this section.

(27) [Reserved]

(28) It is a medicated feed for beef cattle containing bacitracin methylene disalicylate with or without diethylstilbestrol in the amounts and for the purposes specified in § 121.252 of this chapter and its labeling bears adequate directions and warnings for such use.

(29)–(37) [Reserved]

(38) It is intended for use solely for accelerating weight gains in sheep; its labeling bears adequate directions and warnings for such use, including a warning that its use must be discontinued 7 days before the treated animals are slaughtered for human consumption; it contains a quantity of diethylstilbestrol adequate to provide not more than 2 milligrams per head per day when fed in accordance with the directions for use that accompany the feed; it contains less than 50 grams of antibiotics per ton of feed; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind required for Form FD–1800 and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approved supplement to the application provides for the change or the change is made in conformance with other provisions of § 514.9 of this chapter.

(39) It is intended for use solely as an aid in the treatment of fowl typhoid, paratyphoid, and pullorum disease in poultry flocks; its labeling bears adequate directions and warnings for such use, including a warning against its use in laying hens and a warning that its use must be discontinued 48 hours before the treated animals are slaughtered for human consumption; and it contains 3,5-dinitrobenzamide in a quantity, by weight of feed, of not less than 0.075 percent and not more than 0.15 percent; it contains less than 50 grams of antibiotics per ton of feed; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind required for Form FD–1800—Revised under § 514.2 of this chapter, and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approved supplement to the application provides for the change or the change is made in conformance with other provisions of § 514.8 of this chapter. When intended for the uses specified in this paragraph, it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section. If it contains one of the arsenic compounds prescribed in paragraph (a) of this section, its labeling must bear a warning that it must be discontinued 5 days (in lieu of 48 hours as required in this paragraph (b)(39)) before the treated chickens or turkeys are slaughtered for human consumption.

(40)–(51) [Reserved]

(52) It is a cattle feed containing zinc bacitracin, with or without diethylstilbestrol, in the amounts and for the purposes indicated in § 121.225 or § 121.241 of this chapter, and its labeling bears adequate directions and warnings for such use; *Provided, however,* That if such feed contains diethylstilbestrol it is exempt from certification only under the condition that there has been submitted

to the Commissioner, in triplicate, adequate information of the kind required for Form FD–1800, and such application has been approved by the Food and Drug Administration. The exemption shall expire at the beginning of any act changing the labeling or potency of such drug unless an approved supplement to the application provides for the change or the change is made in conformance with other provisions of § 514.9 of this chapter.

(c) It is intended for use as follows:

Product	Species	Use levels	Indications for use
1. Nicarbazin	Chickens	0.01 to 0.02 percent	For use solely in the prevention of outbreaks of coccidiosis in poultry flocks.
Procaine penicillin	do	2.4 to 50 g/ton	Do.
2. Nicarbazin	do	0.01 to 0.02 percent	
Bacitracin methylene disalicylate.	do	4 to 50 g/ton	
3. Nicarbazin	do	0.01 to 0.02 percent	For use as an aid in the prevention of coccidiosis in poultry flocks.
Bacitracin methylene disalicylate.	do	4 to 50 g/ton	
3-Nitro-4-hydroxyphenylarsonic acid.	do	0.0025 to 0.005 percent	
4. Nicarbazin	do	0.01 to 0.02 percent	Do.
Procaine penicillin	do	2.4 to 50 g/ton	
3-Nitro-4-hydroxyphenylarsonic acid.	do	0.0025 to 0.005 percent	
5. Procaine penicillin	Swine	1.5 to 7.5 g/ton	Increase rate of gain and improve feed efficiency in growing swine; aid in the prevention of bacterial swine enteritis.
Streptomycin	do	7.5 to 37.5 g/ton	
Arsanilic acid	do	45 to 90 g/ton	
6. Penicillin	Chickens and turkeys.	2.4 to 25 g/ton	For use solely as a treatment for complicated chronic respiratory disease (air-sac infection), infectious sinusitis, blue comb (nonspecific infectious enteritis, mud fever), and hexamitiasis in poultry; as an aid in maintaining or increasing egg production of chickens, hatchability of eggs, prevention of early mortality of chicks when due to organisms that are sensitive to streptomycin and penicillin; and for improving feed efficiency of chickens or turkeys.
Streptomycin	do	15 to 75 g/ton.	
7. Penicillin	Swine	5 to 25 g/ton	For use in the prevention or treatment of bacterial swine enteritis.
Streptomycin	do	15 to 75 g/ton.	
8. Furazolidone and	Chickens and turkeys.	0.011 percent	Growth promotion and feed efficiency. For prevention of fowl typhoid, paratyphoid, and pullorum in chickens and turkeys when fed for the first 2 weeks of the birds' life. For treatment of fowl typhoid, paratyphoid and pullorum in chickens and turkeys when fed for at least 2 weeks, except when paratyphoid is due to *S. typhimurium*. For reduction of condemnations due to chronic respiratory disease air-sac complex associated with vaccination stress, feed continuously beginning at least 1 week before vaccination. For prevention of infectious hepatitis when fed continuously during the danger period. For control of coccidiosis in chickens, caused by *E. tenella*, *E. necatrix*, or *E. acervulina* when fed for 5 to 7 days or longer. For prevention of blackhead (histomoniasis, enterohepatitis) in chickens and turkeys when fed continuously. For prevention of paracolon in chickens and turkeys and hexamitiasis in turkeys when fed throughout the danger period. For control of chronic respiratory disease (air-sac), infectious sinusitis, synovitis (arthritis due to filterable agent), nonspecific enteritis (blue comb, mud fever) and quail disease (ulcerative enteritis) when fed for 5 to 10 days. (NOTE.—Severe outbreaks may require twice the level specified; i.e., 0.022 percent.)
Bacitracin methylene disalicylate	do	4–50 g/ton	
or—			
Zinc bacitracin or Procaine penicillin.	do	2.4 to 50 g/ton	
9. Furazolidone and	Chickens and turkeys.	0.011 to 0.022 percent	Growth promotion and feed efficiency. Aid in maintenance of feed consumption and growth and reduction of mortality and morbidity due to stress; for the control of the following nonspecific conditions: chronic respiratory disease (air-sac), infectious sinusitis, synovitis (arthritis due to a filterable agent), nonspecific enteritis (blue comb, mud fever) and quail disease (ulcerative enteritis) when fed 5 to 10 days. Follow with preventive level to prevent recurrence.
Bacitracin methylene disalicylate	do	4 to 50 g/ton	
or—			
Zinc bacitracin or Procaine penicillin.	do	2.4–50 g/ton	

Product	Species	Use levels	Indications for use
10. Furazolidone and— Bacitracin methylene disalicylate or— Zinc bacitracin or Procaine penicillin.	Chickens and turkeys.	0.22 percent	For treatment of paratyphoid due to *S. typhimurium* when fed for 2 weeks. For treatment of blackhead (histomoniasis, enterohepatitis) in chickens and turkeys when fed for 2 to 3 weeks (following diagnosis). For treatment of paracolon in chickens and turkeys and hexamitiasis in turkeys when fed for 2 weeks or longer (following diagnosis). For control of chronic respiratory disease (air-sac), infectious sinusitis, synovitis (arthritis due to filterable agent), mud fever and quail disease (ulcerative enteritis) when fed for 5 to 10 days. For treatment of infectious hepatitis in chickens when fed for 14 days and repeated as necessary.
	....do	4 to 50 g/ton	
	....do	2.4 to 50 g/ton	
11. Chlortetracycline	Swine	10 to 50 g/ton	Enhancement of growth and feed efficiency.
Arsanilic acid	....do	0.005 to 0.01 percent	As an aid in the reduction of losses due to enterotoxemia.
12. Chlortetracycline	Sheep	20 g/ton	It is intended for use as an aid in reducing the incidence of vibrionic abortion in breeding sheep; it is to be administered continuously during pregnancy.
13. Chlortetracycline	....do	80 mg per head per day	As an aid in the reduction of bacterial diarrhea in dairy cattle or as an aid in reduction of losses due to respiratory infection (infectious rhinotracheitis—shipping fever complex) or as an aid in the prevention of foot rot in cattle.
14. Chlortetracycline	Cattle	Feed contains the following quantities of chlortetracycline, by weight, for the conditions indicated: (1) For the prevention of foot rot and as an aid in the reduction of bacterial diarrhea in dairy cattle; 0.1 mg/lb of body weight per day; and (2) as an aid in the reduction of losses due to respiratory infection (infectious rhinotracheitis—shipping fever complex) in dairy cattle: 0.1 mg/lb of body weight per day, except that if it is intended for use for more than 30 days it may contain chlortetracycline, in a quantity by weight of feed to provide 70 mg per head per day.	

18. In § 558.15 by adding a new paragraph (g) to read as follows:

§ 558.15 Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals.

* * * * *

(g) The submission of applications and data required by paragraphs (a) and (b) of this section is not required for the continued manufacture of any intermediate premix which is produced solely from a premix that is in compliance with the requirements of this section: *Provided,* That the intermediate premix contains no drug ingredient whose use in or on animal feed requires an approved application pursuant to section 512(m) of the act and/or where the premix is approved by regulation in this part.

(1) The following antibacterial drug premixes manufactured by the designated sponsors are eligible for interim marketing based on their compliance with the requirements of this section:

Drug sponsor	Drug premix	Species	Use levels	Indications for use
Commercial Solvents Corp., Thompson-Hayward Chemical Co.	Zinc bacitracin	Chickens, turkeys, swine, pheasants, and quail.	Sec. 121.232 (tables 1 and 2) of this chapter.	Sec. 121.232 (tables 1 and 2) of this chapter.
Do	do	Cattle	Sec. 121.225 of this chapter.	Sec. 121.225 of this chapter.
S. B. Penick & Co., Diamond Shamrock Chemical Co.	Bacitracin methylene disalicylate.	Chickens, turkeys, and swine.	Sec. 121.252 (tables 1 and 2) of this chapter.	Sec. 121.252 (tables 1 and 2) of this chapter.
Do	do	Cattle	Sec. 121.225 of this chapter.	Sec. 121.225 of this chapter.
Do	do	do	Sec. 121.252 (table 3) of this chapter.	Sec. 121.252 (table 3) of this chapter.
Elanco Products Co.	Hygromycin B	Chickens and swine.	Sec. 121.213 (tables 1 and 2) of this chapter.	Sec. 121.213 (tables 1 and 2) of this chapter.
Do	Tylosin	Chickens, swine, and beef cattle.	Sec. 558.625	Sec. 558.625.
Abbott Laboratories	Erythromycin	Chickens, turkeys, and swine.	Sec. 121.292 of this chapter.	Sec. 121.292 of this chapter.
The Upjohn Co	Lincomycin	Chickens	Sec. 558.325	Sec. 558.325.
Pfizer, Inc	Oleandomycin	Chickens, turkeys, and swine.	Sec. 558.435	Sec. 558.435.
Hoechst Pharmaceuticals.	Bambermycins	Chickens	Sec. 558.95	Sec. 558.95.
Elanco Products Co.	Tylosin	Swine	Sec. 558.630	Sec. 558.630.
Do	Sulfamethazine	do	do	Do.
American Cyanamid Co., Diamond-Shamrock Chemical Co., Hess & Clark, Rachelle Labs, Inc., and Vitamin Premixers of Omaha.	Chlortetracycline	Chickens, turkeys, swine, and cattle.	Sec. 121.208 (tables 1, 2, and 6) of this chapter.	Sec. 121.208 (tables 1, 2, and 6) of this chapter.
			Sec. 121.225 of this chapter.	Sec. 121.225 of this chapter.
Merck Sharp & Dohme Research Labs.	Procaine penicillin.	Chickens, turkeys, swine, pheasant, and quail.	Sec. 121.256 (tables 1 and 2) of this chapter.	Sec. 121.256 (tables 1 and 2) of this chapter.
			Sec. 121.225 of this chapter.	Sec. 121.225 of this chapter.
E. R. Squibb & Sons, Inc.	do	do	do	Do.
Merck Sharp & Dohme Research Labs.	Sulfaquinoxaline	Chickens	Continuously, 0.0125 to 0.025 percent.	Aid in prevention of coccidiosis due to *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. maxima.*
Do	do	Turkeys	Continuously, 0.0175 percent.	Aid in the prevention of coccidiosis due to *Eimeria meleagrides, E. meleagrimites* and *E. adenoides.*
Do	do	Rabbits	Continuously, 0.025 percent.	Aid in prevention of coccidiosis due to *Eimeria stiedae, E. perforans.*
Pfizer, Inc., and Vitamin Premixers of Omaha.	Oxytetracycline	Chickens and turkeys.	Sec. 121.251 (table 1) of this chapter.	Sec. 121.251 (table 1) of this chapter.
Do	do	Swine (10 to 30 lb)	25 to 50 g/ton	To increase rate of gain and improve feed efficiency.
Do	do	Swine (30 to 200 lb).	7½ to 10 g/ton	Do.
Do	do	Swine	50 g/ton	As an aid in the prevention of bacterial enteritis, also known as scours, baby pig diarrhea, vibrio dysentery, bloody dysentery, and salmonellosis (necro or necrotic enteritis).
Do	do	do	100 g/ton	As an aid in the treatment of bacterial enteritis, also known as scours, baby pig diarrhea, vibrio dysentery, bloody dysentery, and salmonellosis (necro or necrotic enteritis).
Do	do	do	50 to 150 g/ton	As an aid in the maintenance of weight gains and feed consumption in presence of atrophic rhinitis.
Do	do	do	500 g/ton	In presence of porcine leptospirosis reduces instances of abortion, gives higher survival rate, heavier and healthier newborn pigs, reduces urinary shedding of leptospirae and aids in maintenance of normal weight gains and feed consumption. Feed 7 to 14 days, approximately 1 month before farrowing.
Do	do	Calves	0.05 to 0.1 mg/lb of body weight daily or 25 to 75 mg per head daily.	To increase rate of gain and improve feed efficiency.

Drug sponsor	Drug premix	Species	Use levels	Indications for use
Pfizer Inc., and Vitamin Premixers of of Omaha—Con.	Oxytetracycline	Calves	0.5 mg/lb of body weight daily or in complete feed at 50 g/ton.	As an aid in the prevention of bacterial diarrhea.
Do	do	do	0.5 to 5.0 mg/lb of body weight daily or complete feed at 50 g/ton.	As an aid in the treatment of bacterial diarrhea.
Do	do	Cattle	75 to 80 mg per head daily.	As an aid in reducing incidence and severity of bloat. As an aid in reducing incidence and severity of liver abscesses (for cattle weighing over 400 lb). To increase rate of gain and improve feed efficiency. As an aid in increasing milk production in lactating dairy cows.
Do	do	do	0.1 to 0.5 mg/lb of body weight daily.	As an aid in the prevention of bacterial diarrhea.
Do	do	do	0.5 to 5.0 mg/lb of body weight daily.	As an aid in the treatment of bacterial diarrhea, also known as scours.
Do	do	do	0.5 to 2.0 g per head daily.	For the prevention and treatment of the early stages of shipping fever complex. Oxytetracycline is effective prophylaxis when fed 3 to 5 days preceding shipment and/or 3 to 5 days following arrival in feed-lots. For treatment of shipping fever, these levels should be fed at onset of the disease symptoms until symptoms disappear.
Do	do	Sheep	10 to 20 g/ton	To increase rate of gain and improve feed efficiency during finishing period.
Do	do	do	50 g/ton	As an aid in the prevention of bacterial diarrhea, also known as scours, lamb dysentery, and white scours of lambs.
Do	do	do	100 g/ton	As an aid in the treatment of bacterial diarrhea, also known as scours, lamb dysentery, and white scours of lambs.
Do	do	do	25 mg per head daily.	As an aid in reduction of losses due to enterotoxemia, also known as overeating disease.
Pfizer, Inc	Penicillin	Chickens, turkeys, and swine.	Secs. 121.225, 121.256, and 510.515 of this chapter.	Secs. 121.225, 121.256, and 510.515 of this chapter.
Do	Penicillin and streptomycin.	do	do	Do.
American Cyanamid Co.	Chlortetracycline	Cattle	Sec. 121.208 (table 6) of this chapter.	Sec. 121.208 (table 6) of this chapter.
Do	Sulfamethazine	do	do	Do.
Norwich Pharmacal	Nitrofurazone	Swine	0.055 percent (500 g/ton).	Treatment of necrotic enteritis caused by *S. choleraesuis*.
Merck Sharp & Dohme Research Labs.	Procaine penicillin and streptomycin sulfate.	Secs. 121.225 and 121.256 of this chapter.	Secs. 121.225 and 121.256 of this chapter.	Secs. 121.225 and 121.256 of this chapter.
Abbott Laboratories	Erythromycin	Cattle	37 mg per head per day.	Sec. 121.225 of this chapter.
Hoffman-LaRoche, Inc.	Sulfadimethoxine and ormetoprim.	Chickens and turkeys.	Sec. 558.575	Sec. 558.575.
Pfizer, Inc	Oxytetracycline and neomycin.	Chickens, turkeys, swine, and calves.	As provided in paragraph (g)(2) of this section.	As provided in paragraph (g)(2) of this section.
American Cyanamid Co. and Rochelle Labs, Inc.	Chlortetracycline, sulfamethazine, and penicillin.	Swine	do	Do.
Diamond Shamrock Chemical Co.	Chlortetracycline, sulfathiazole, and penicillin.	do	do	Do.

Drug sponsor	Drug premix	Species	Use levels	Indications for use
Hess & Clark and Norwich Pharmacal Co.	Furazolidone	Chickens and turkeys.	0.00082 to 0.0011 percent (7½ to 10 g/ton).	To stimulate growth and improve feed efficiency of chickens and turkeys when fed continuously.
Do	do	do	0.0055 percent (50 g/ton).	For prevention of fowl typhoid, paratyphoid, and pullorum in chickens and turkeys when fed continuously in birds older than 2 weeks of age. For aid in prevention of coccidiosis in chickens caused by *E. tenella*, *E. necatrix*, or *E. acervulina* when fed continuously.
Do	do	do	0.0055–0.011 percent (50–100 g/ton).	Aid in maintenance of feed consumption and growth and reduction of morbidity and mortality due to stress and the following nonspecific conditions: Chronic respiratory disease (air-sac), infectious sinusitis, synovitis (arthritis due to filterable agent), nonspecific enteritis (blue comb, mud fever) and quail disease (ulcerative enteritis) when fed continuously prior to or throughout the danger period and during times of stress.
Do	do	do	0.011 percent (100g/ton).	For prevention of fowl typhoid, paratyphoid and pullorum in chickens and turkeys when fed for the first 2 weeks of the birds' life and followed continuously thereafter by ½ this level (i.e., 0.0055 percent). For treatment of fowl typhoid, paratyphoid, and pullorum in chickens and turkeys when fed for at least 2 weeks except when paratyphoid is due to *S. typhimurium*.
Do	do	do	do	For reduction of condemnations due to chronic respiratory disease air-sac complex associated with vaccination stress, feed continuously beginning at least 1 week before vaccination. For prevention of infectious hepatitis when fed continuously during the danger period. For control of coccidiosis in chickens caused by *E. tenella*, *E. necatrix*, or *E. acervulina* when fed for 5 to 7 days or longer and followed by ½ this level (i.e., 0.0055 percent) for 2 weeks to aid in preventing recurrence.
Do	do	do	do	For prevention of black head (histomoniasis, enterohepatitis) in chickens and turkeys when fed continuously. For prevention of paracolon in chickens and turkeys and hexamitiasis in turkeys when fed throughout the danger period. For control of chronic respiratory disease (air-sac), infectious sinusitis, synovitis (arthritis due to filterable agent), nonspecific enteritis (blue comb, mud fever) and quail disease (ulcerative enteritis) when fed for 5 to 10 days and followed with ½ this level (i.e., 0.0055 percent) to aid in preventing recurrence. (NOTE.—Severe outbreaks may require twice the level specified; i.e., 0.022 percent).

Drug sponsor	Drug premix	Species	Use levels	Indications for use
Hess & Clark and Norwich Pharmaceutical Co.	Furazolidone	Chickens and turkeys	0.011 to 0.022 percent (100 to 200 g/ton).	Aid in maintenance of feed consumption and growth, and reduction of mortality and morbidity due to stress; for the control of the following nonspecific conditions: Chronic respiratory disease (air-sac), infectious sinusitis, synovitis (arthritis due to a filterable agent), (blue comb, mud fever), and quail disease (ulcerative enteritis) when fed 5 to 10 days. Follow with preventive level to prevent recurrence.
Do	do	do	0.022 percent (200 g/ton.	For treatment of paratyphoid due to *S. typhimurium* when fed for 2 weeks. For treatment of blackhead (histomoniasis, enterohepatitis) in chickens and turkeys when fed for 2 to 3 weeks (following diagnosis). For treatment of paracolon in chickens and turkeys and hexamitiasis in turkeys when fed for 2 weeks or longer (following diagnosis). For control of chronic respiratory disease (air-sac), infectious sinusitis, synovitis (arthritis due to filterable agent), nonspecific enteritis (blue comb, mud fever), and quail disease (ulcerative enteritis) when fed for 5 to 10 days and followed with ¼ this level (i.e., 0.0055 percent) to aid in preventing recurrences. For treatment of infectious hepatitis in chickens when fed for 14 days and repeated as necessary.
Do	do	Swine	Sec. 121.255 of this chapter.	Sec. 121.255 of this chapter.
Do	Nitrofurazone	Chickens	0.0055 percent (50g/ton).	Aid in prevention of coccidiosis when fed continuously.
Do	do	Turkeys	do	As an aid in controlling losses due to secondary bacterial invasions concurrent with coccidiosis outbreaks when fed continuously throughout the danger period.
Do	Nihydrazone	Chickens	Sec. 121.237 of this chapter.	Sec. 121.237 of this chapter.

(2) The following is a list of drug combinations permitted when prepared from antibacterial drug premixes listed in paragraph (g)(1) of this section. Drug combinations listed in Subpart B of this part name their sponsors and are incorporated herein by reference since they are safe and effective by contemporary standards, or such sponsors have been notified of any additional safety or efficacy data required on an individual basis:

Drug sponsor	Drug ingredient	Species	Use levels	Indications for use
Diamond Shamrock Chemical Co.	Chlortetracycline	Swine	10 to 50 g/ton	Enhancement of growth and feed efficiency.
Do	Arsanilic acid	do	0.005 to 0.01 percent.	Do.
American Cyanamid Co.	Chlortetracycline and sulfamethazine.	Cattle	Sec. 121.208 (table 6) of this chapter.	Sec. 121.208 (table 6) of this chapter.
Pfizer, Inc., and Vitamin Premixers of Omaha.	Oxytetracycline	Chickens	50 g/ton	Prevention of diseases from oxytetracycline susceptible organisms during periods of stress. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with blue comb (mud fever or nonspecific enteritis).
Do	Neomycin base	do	35 to 140 g/ton	Prevention of early chick mortality due to oxytetracycline-susceptible organisms. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with blue comb (mud fever or nonspecific enteritis).
Do	Oxytetracycline	Chickens (1st 2 weeks).	50 to 100 g/ton	Do.
Do	Neomycin base	do	35 to 140 g/ton	To extend period of high egg production, to improve feed efficiency, to improve egg production and feed efficiency in presence of disease and at time of stress: As an aid in maintaining and improving hatchability where birds are suffering stress from moving, vaccinations, culling, extreme temperature changes, and worming; to improve livability of progeny when losses are due to oxytetracycline-susceptible organisms, to improve egg shell quality, prevention of blue comb (mud fever or nonspecific enteritis). As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with blue comb (mud fever or non specific enteritis).
Do	Oxytetracycline	Chickens	50 to 100 g/ton	Do.
Do	Neomycin base	do	35 to 140 g/ton	Prevention of complicated chronic respiratory disease (air-sac infection) and control of complicated chronic respiratory disease by lowering mortality and severity during outbreaks. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with blue comb (mud fever or nonspecific enteritis).
Do	Oxytetracycline	do	100 to 200 g/ton	Do.
Do	Neomycin base	do	35 to 140 g/ton	As an aid in the prevention of disease from oxytetracycline-susceptible organisms during periods of stress. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with blue comb (mud fever or nonspecific enteritis).
Pfizer, Inc	Oxytetracycline	Turkeys	50 g/ton	Do.

Drug sponsor	Drug ingredient	Species	Use levels	Indications for use
Pfizer, Inc.....Con.	Neomycin base.....	do.....	35 to 140 g/ton.....	
Do.....	Oxytetracycline.....	do.....	50 to 100 g/ton.....	To extend period of high egg production, to improve egg production, to improve feed efficiency, to improve fertility, to improve egg production and feed efficiency in presence of disease and time of stress; as an aid in maintaining and improving hatchability where birds are suffering from stress, exposure, moving, vaccination, culling, extreme losses due to oxytetracycline-susceptible organisms, and t improve egg shell quality prevention of hexamitia sis As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with blue comb (mud fever or nonspecific enteritis).
Do.....	Neomycin base.....	do.....	35 to 140 g/ton.....	Do.
Do.....	Oxytetracycline.....	Turkeys (first 4 weeks).	50 to 100 g/ton.....	As an aid in the prevention of early poult mortality due to oxytetracycline-susceptible organisms. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with blue comb (mud fever or nonspecific enteritis).
Do.....	Neomycin base.....	do.....	35 to 140 g/ton.....	Do.
Do.....	Oxytetracycline.....	do.....	100 to 150 g/ton.....	As an aid in reducing mortality in birds which have suffered an attack of air-sacculitis (it is recommended, wherever possible, to feed from time of attack to marketing).
Do.....	Neomycin base.....	do.....	35 to 100 g/ton.....	Do.
Do.....	Oxytetracycline.....	Turkeys.....	100 to 150 g/ton.....	As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with blue comb (mud fever or nonspecific enteritis).
Do.....	Neomycin base.....	do.....	35 to 100 g/ton.....	Do.
Do.....	Oxytetracycline.....	do.....	100 to 200 g/ton.....	Control of blue comb (mud fever or nonspecific enteritis), infectious sinusitis and hexamitiasis, prevention of infectious synovitis. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with blue comb (mud fever or nonspecific enteritis).
Do.....	Neomycin base.....	do.....	35 to 140 g/ton.....	Do.
Do.....	Oxytetracycline.....	do.....	200 g/ton.....	Control of infectious synovitis. For the treatment of bacterial enteritis and blue comb (mud fever or nonspecific enteritis).
Do.....	Neomycin base.....	do.....	70 to 140 g/ton.....	Do.
Pfizer, Inc., and Vitamin Premixers of Omaha.	Oxytetracycline.....	Swine.....	50 g/ton.....	As an aid in the prevention of bacterial enteritis (scours), baby pig diarrhea (in baby pigs only), vibrionic dysentery, bloody dysentery and salmonellosis (necro or necrotic enteritis).
Do.....	Neomycin base.....	do.....	35 to 140 g/ton.....	Do.
Do.....	Oxytetracycline.....	do.....	50 to 150 g/ton.....	As an aid in the maintenance of weight gains and feed consumption in the presence of atrophic rhinitis. As an aid in the treatment of bacterial enteritis.
Do.....	Neomycin base.....	do.....	70 to 140 g/ton.....	Do.
Pfizer, Inc.....	Oxytetracycline.....	Calves.....	50 g/ton.....	As an aid in the prevention of bacterial enteritis (scours).
Do.....	Neomycin base.....	do.....	35 to 140 g/ton.....	Do.
Do.....	Oxytetracycline.....	do.....	100 g/ton.....	As an aid in the treatment of bacterial enteritis (scours).
Do.....	Neomycin base.....	do.....	70 to 140 g/ton.....	Do.

Drug sponsor	Drug ingredient	Species	Use levels	Indications for use
Pfizer, Inc.—Con.	Oxytetracycline	Calves	5 to 100 mg/gal reconstituted milk replacer.	As an aid in the prevention of bacterial diarrhea (scours).
Do	Neomycin base	do	100 to 200 mg/gal reconstituted milk replacer.	Do.
Do	Oxytetracycline	do	40 to 200 mg/gal reconstituted milk replacer.	Do.
Do	Neomycin base	do	200 to 400 mg/gal reconstituted milk replacer.	Do.
The Upjohn Co	Lincomycin, amprolium, and ethopabate.	Chickens	Secs. 558.325 and 121.210 of this chapter.	Secs. 558.325 and 121.210 of this chapter.
Do	Lincomycin and zoalene.	do	Secs. 558.325 and 121.207 of this chapter.	Secs. 558.325 and 121.207 of this chapter.
Do	Lincomycin, amprolium, ethopabate, and 3-nitro-4-hydroxyphenylarsonic acid.	do	Secs. 558.325 and 121.210 and 121.262 of this chapter.	Secs. 558.325 and 121.210 and 121.262 of this chapter.
Do	Lincomycin, monensin, and 3-nitro-4-hydroxyphenylarsonic acid.	do	Secs. 558.325 and 558.355 and 121.262 of this chapter.	Secs. 558.325 and 558.355 and 121.262 of this chapter.
Merck Sharp & Dohme Research Labs. and Pfizer, Inc.	Procaine penicillin.	Chickens and turkeys.	2.4 to 7.5 g/ton	Sec. 121.225(a)(3)(iii) of this chapter.
Do	Streptomycin	do	12.0 to 37.5 g/ton	Do.
Do	Procaine penicillin.	Chickens	3.75 to 7.5 g/ton	Do.
Do	Streptomycin	do	18.75 to 37.5 g/ton	Do.
Do	Procaine penicillin.	do	3.75 to 30 g/ton	Sec. 121.256 (table 1) of this chapter.
Do	Streptomycin	do	18.75 to 150 g/ton	Do.
Do	Procaine penicillin.	Turkeys	15 to 30 g/ton	Do.
Do	Streptomycin	do	75 to 150 g/ton	Do.
Do	Procaine penicillin.	Chickens	2.4 to 25 g/ton	Sec. 510.515 of this chapter.
Do	Streptomycin	do	15 to 75 g/ton	Do.
Do	Procaine penicillin.	Swine	1.5 to 7.5 g/ton	Sec. 121.225(a)(3)(iv) of this chapter.
Do	Streptomycin	do	7.5 to 37.5 g/ton	Do.
Do	Procaine penicillin.	do	7.5 to 45 g/ton	Sec. 121.256 (table 2) of this chapter.
Do	Streptomycin	do	37.5 to 225 g/ton	Do.
Do	Procaine penicillin.	do	5 to 25 g/ton	Sec. 510.515 of this chapter.
Do	Streptomycin	do	15 to 75 g/ton	Do.
Merck Sharp & Dohme Research Labs.	Procaine penicillin.	do	1.5 to 7.5 g/ton	Do.
Do	Streptomycin	do	7.5 to 37.5 g/ton	Do.
Do	Arsanilic acid	do	45 to 90 g/ton	Do.
Do	Nicarbazin	Chickens	0.01 to 0.02 percent.	Do.
Do	Procaine penicillin.	do	2.4 to 50 g/ton	Do.
Do	Nicarbazin	do	0.01 to 0.02 percent.	Do.
Do	Bacitracin methylene disalicylate.	do	4 to 50 g/ton	Do.
Do	Nicarbazin	do	0.01 to 0.02 percent.	Do.
Do	Bacitracin methylene disalicylate.	do	4 to 50 g/ton	Do.
Do	3-nitro-4-hydroxyphenylarsonic acid.	do	0.0025 to 0.005 percent.	Do.
Do	Nicarbazin	do	0.01 to 0.02 percent.	Do.
Do	Procaine penicillin.	do	2.4 to 50 g/ton	Do.
Do	3-nitro-4-hydroxyphenylarsonic acid.	do	0.0025 to 0.025 percent.	Do.
Do	Amprolium	Chickens and turkeys.	0.0125 to 0.025 percent.	Sec. 121.210 of this chapter.
Do	Bacitracin methylene disalicylate.	do	4 to 50 g/ton	Do.
Do	Amprolium	Chickens	0.0125 to 0.025 percent.	Do.
Do	Ethopabate	do	0.0004 percent	Do.
Do	Bacitracin methylene disalicylate.	do	4 to 50 g/ton	Do.
Do	Amprolium	do	0.0125 to 0.025 percent.	Secs. 121.210 and 121.262 of this chapter.
Do	Ethopabate	do	0.0004 percent	Do.
Do	Bacitracin methylene disalicylate.	do	4 to 50 g/ton	Do.
Do	3-nitro-4-hydroxyphenylarsonic acid.	do	0.0025 to 0.005 percent.	Do.

Drug sponsor	Drug ingredient	Species	Use levels	Indications for use
Merck Sharp & Dohme Research Labs.—Con.	Amprolium	Chickens and turkeys.	0.004 to 0.025 percent.	Sec. 121.210 of this chapter.
Do	Procaine penicillin	do	2.4 to 50 g/ton	Do.
Do	Amprolium	Chickens	0.004 to 0.025 percent.	Secs. 121.210 and 121.262 of this chapter.
Do	Procaine penicillin.	do	2.4 to 50 g/ton	Do.
Do	3-nitro-4-hydroxyphenylarsonic acid.	do	0.0025 to 0.005 percent.	Do.
Do	Amprolium	do	0.0125 to 0.025 percent.	Sec. 121.210 of this chapter.
Do	Ethopabate	do	0.0004 percent	Do.
Do	Procaine penicillin.	do	2.4 to 50 g/ton	Do.
Do	Erythromycin	do	4.6 to 18.5 g/ton	Do.
Do	Amprolium	do	0.0125 to 0.025 percent.	Do.
Do	Erythromycin	do	4.6 to 18.5 g/ton	Do.
Do	Amprolium	do	0.0125 to 0.025 percent.	Do.
Do	Ethopabate	do	0.0004 percent	Do.
Do	Amprolium	do	0.0125 to 0.025 percent.	Do.
Do	Arsanilic acid	do	0.01 percent	Do.
Do	Erythromycin	do	4.6 to 18.5 g/ton	Do.
Do	Amprolium	do	0.0125 to 0.025 percent.	Do.
Do	Arsanilic acid	do	0.01 percent	Do.
Do	Ethopabate	do	0.0004 percent	Do.
Do	Amprolium	do	0.0125 percent	Do.
Do	Ethopabate	do	0.004 percent	Do.
Do	Bacitracin methylene disalicylate.	do	4 to 50 g/ton	Do.
Do	Amprolium	do	0.0125 percent	Do.
Do	Ethopabate	do	0.004 percent	Do.
Do	Bacitracin methylene disalicylate.	do	5 to 35 g/ton	Do.
Do	3-nitro-4-hydroxyphenylarsonic acid.	do	0.00375 percent	Do.
Commercial Solvents Corp.	Zinc bacitracin	do	4 to 50 g/ton	Prevention of coccidiosis. Growth promotion and feed efficiency. Sec. 121.233 of this chapter.
Do	Amprolium	do	0.0125 to 0.025 percent.	Do.
Do	Ethopabate	do	0.0004 percent	Do.
Do	Zinc bacitracin	do	4 to 50 g/ton	Prevention of coccidiosis. Growth promotion and feed efficiency. Improving pigmentation. Sec. 121.233 of this chapter.
Do	Amprolium	do	0.0125 to 0.025 percent.	Do.
Do	Ethopabate	do	0.0004 percent	Do.
Do	3-nitro-4-hydroxyphenylarsonic acid.	do	0.0025 to 0.005 percent.	Do.
Do	Zinc bacitracin	Swine	10 to 50 g/ton	Increased rate of weight gain and improved feed efficiency.
Do	Arsanilic acid	do	0.005 to 0.01 percent.	Do.
Merck Sharp & Dohme Research Labs.	Amprolium	do	0.0125 to 0.025 percent.	Secs. 121.210 and 121.262 of this chapter.
Do	Ethopabate	do	0.0004 percent	Do.
Do	Procaine penicillin.	do	2.4 to 50 g/ton	Do.
Do	3-nitro-4-hydroxyphenylarsonic acid.	do	0.0025 to 0.005 percent.	Do.
Pfizer, Inc	Penicillin	Chickens and turkeys.	2.4 to 25 g/ton	Sec. 510.515 of this chapter.
Do	Streptomycin	do	15 to 75 g/ton	Do.
Do	Penicillin	Swine	5 to 25 g/ton	Do.
Do	Streptomycin	do	15 to 75 g/ton	Do.
Dow Chemical Co	Zoalene	Chickens	0.0125 percent	Sec. 121.207 of this chapter.
Do	Bacitracin methylene disalicylate.	do	4 to 50 g/ton	Do.
Do	Zoalene	do	0.0125 percent	Do.
Do	3-nitro-4-hydroxyphenylarsonic acid.	do	0.005 percent	Do.
Do	Bacitracin methylene disalicylate.	do	4 to 50 g/ton	Do.
Do	Zoalene	do	0.0125 percent	Do.
Do	Zinc bacitracin	do	4 to 50 g/ton	Do.
Do	Zoalene	do	0.0125 percent	Do.
Do	3-nitro-4-hydroxyphenylarsonic acid.	do	0.005 percent	Do.
Do	Zinc bacitracin	do	4 to 50 g/ton	Do.

Drug sponsor	Drug ingredient	Species	Use levels	Indications for use
Dow Chemical Co.—Con.	Zoalene	Chickens	0.0125 percent	Do.
Do	Penicillin	do	2.4 to 50 g/ton	Do.
Do	Zoalene	do	0.0125 percent	Do.
Do	3-nitro-4-hydroxyphenylarsonic acid.	do	0.005 percent	Do.
Do	Penicillin	do	2.4 to 50 g/ton	Do.
Do	Zoalene	do	0.0125 percent	Do.
Do	Arsanilic acid	do	0.01 percent	Do.
Do	Bacitracin methylene disalicylate or zinc bacitracin.	do	4 to 50 g/ton	Do.
Do	Zoalene	do	0.0125 percent	Do.
Do	Arsanilic acid	do	0.01 percent	Do.
Do	Penicillin	do	2.4 to 50 g/ton	Do.
Do	Zoalene	do	0.004 to 0.0125 percent.	Do.
Do	Bacitracin methylene disalicylate.	do	4 to 50 g/ton	Do.
Do	Zoalene	do	0.004 to 0.0125 percent.	Do.
Do	3-nitro-4-hydroxyphenylarsonic acid.	do	0.005 percent	Do.
Do	Bacitracin methylene disalicylate.	do	4 to 50 g/ton	Do.
Norwich Pharmacal Co.	Furazolidone	Swine	0.022 percent (200 g/ton).	Prevention of bacterial enteritis (necrotic enteritis, necro) and vibrionic (bloody) dysentery; growth promotion while on medication when fed in prestarters, starters, and growing rations to baby pigs and growing swine for 2 weeks. As an aid in the maintenance of weight gains and feed consumption in presence of atrophic rhinitis.
Do	Oxytetracycline	do	50 to 150 g/ton	Do.
Do	Furazolidone	do	0.011 percent (100 g/ton).	Prevention of bacterial enteritis (necrotic enteritis, necro) and vibrionic (bloody) dysentery; growth promotion while on medication when fed in prestarters, starters, and growing rations to baby pigs and growing swine for 5 weeks. As an aid in the maintenance of weight gains and feed consumption in presence of atrophic rhinitis. Growth promotion and feed efficiency.
Do	Oxytetracycline	do	50 to 100 g/ton	Do.
Do	Arsanilic acid	do	0.005 to 0.01 percent.	Do.
Do	Furazolidone and	Chickens and turkeys.	0.011 to 0.022 percent (100 to 200 g/ton).	Sec. 510.515 of this chapter.
Do	Bacitracin methylene disalicylate or—	do	4 to 50 g/ton	Do.
Do	Zinc bacitracin or Procaine penicillin.	do	2.4 to 50 g/ton	Do.
Do	Nihydrazone	Chickens	0.011 percent (100 g/ton).	Sec. 121.237 of this chapter.
Do	Procaine penicillin.	do	2.4 to 50 g/ton	Do.
Do	Nihydrazone	do	0.011 percent (100 g/ton).	Do.
Do	Chlortetracycline	do	10 to 50 g/ton	Do.
Do	Nihydrazone	do	0.011 percent (100 g/ton).	Sec. 121.237 of this chapter.
Do	Bacitracin methylene disalicylate or zinc bacitracin.	do	4 to 50 g/ton	Do.
Do	Furazolidone	Swine	0.011 percent (100 g/ton).	Prevention of bacterial enteritis (necrotic enteritis, necro) and vibrionic (bloody) dysentery; growth promotion while on medication and when fed in prestarters, starters, and growing swine for 5 weeks. As an aid in the maintenance of weight gains and feed consumption in presence of atrophic rhinitis.
Do	Oxytetracycline	do	50 to 150 g/ton	Do.

Drug sponsor	Drug ingredient	Species	Use levels	Indications for use
Norwich Pharmacal Co.—Con.	Furazolidone	Swine	0.0165 percent (150 g/ton).	Prevention of bacterial enteritis (necrotic enteritis, necro) and vibrionic (bloody) dysentery; growth promotion while on medication and when fed in prestarters, starters, and growing swine for 3 weeks. As an aid in the maintenance of weight gains and feed consumption in presence of atrophic rhinitis.
Do	Oxytetracycline	do	50 to 150 g/ton	Do.
Do	Furazolidone	do	0.0165 percent (150 g/ton).	Prevention of bacterial enteritis (necrotic enteritis, necro) and vibrionic (bloody) dysentery; growth promotion while on medication when fed in prestarters, starters, and growing rations to baby pigs and growing swine for 3 weeks. As an aid in the maintenance of weight gains and feed consumption in presence of atrophic rhinitis. Growth promotion and feed efficiency.
Do	Oxytetracycline	do	50 to 100 g/ton	Do.
Do	Arsanilic acid	do	0.005–0.01 percent	Do.
Do	Furazolidone	do	0.022 percent	Prevention of bacterial enteritis (necrotic enteritis, necro) and virbrionic (bloody) dysentery; growth promotion while on medication when fed in prestarters, starters, and growing rations to baby pigs and growing swine for 2 weeks. As an aid in the maintenance of weight gains and feed consumption in presence of atrophic rhinitis. Growth promotion and feed efficiency.
Do	Oxytetracycline	do	50 to 100 g/ton	Do.
Do	Arsanilic acid	do	0.005 to 0.01 percent.	Do.
Whitmoyer Labs. Inc.	Carbarsone and bacitracin.	Turkeys	Sec. 121.310 of this chapter.	Sec. 121.310 of this chapter.

§ 558.19 [Revoked]

19. By revoking § 558.19 *Combination antibiotic drugs in animal feeds no longer sanctioned* and reserving it.

§ 558.35 [Amended]

20. In § 558.35 *Aklomide* by revoking paragraph (g) (5), (6), (7), and (8).

§ 558.505 [Amended]

21. In § 558.505 *Reserpine* by revoking paragraph (g) (2), (3), and (4) and reserving them.

§ 558.625 [Amended]

22. In § 558.625 *Tylosin* by revoking paragraph (f) (1) (iii) (*b*) and reserving it.

Effective date. This regulation shall be effective on March 26, 1976.

(Secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343–351 (21 U.S.C. 360b, 371(a)))

Dated: February 2, 1976.

SAM D. FINE,
Associate Commissioner for Compliance.

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